

US3312629 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:05:01

All time stamps listed in this document are displayed in GMT

US3312629

Form: Participant Creation

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Participant ID

US3312629

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

US3312629

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3312629

Folder: Screening

Form: Demographics

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
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

US3312629

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3312629

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	CURRENT HIATAL HERNIA
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 (5)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	MIGRAINES
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 (7)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	ACID REFLUX
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 (9)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	LAPAROSCOPIC SLEEVE GASTRECTOMY
Start date (dd MMM yyyy)	UN JAN 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 JAN 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	DIVERTICULOSIS
Start date (dd MMM yyyy)	UN JUN 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	TRAMADOL ALLERGY
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	INGUINAL HERNIA
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	EROSIVE ESOPHAGITIS
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	DUODENAL ULCER
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	CHOLECYSTECTOMY
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 (21)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	RIGHT ROTATOR CUFF REPAIR
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 (23)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	LEFT RELEASE OF ULNAR NERVE IN GUYON'S CANAL
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	RIGHT CARPAL TUNNEL SYNDROME
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3312629

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	RIGHT CARPAL TUNNEL SURGERY
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	LEFT CARPAL TUNNEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	LEFT CARPAL TUNNEL SURGERY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3312629

Folder: Screening

Form: Medical History (28)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	CHOLECYSTITIS
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 (29)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (30)

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Condition	RIGHT ROTATOR CUFF TEAR
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: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:06
Height (xxx.x)	65.0 in
Weight (xxx.x)	219.4 lb
BMI (xxx.x)	36.58641 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Date of assessment (dd MMM yyyy) 11 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2018

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 07 Apr 2021 19:39:16

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 113445

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 ☒

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Height	ND - Not Done
Weight	ND - Not Done

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

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)	11 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:06
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	13:57 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 13:57
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

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.

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 13:26 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 13:26

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	12:35 (24 HR)
Collection date and time (derived)	11 SEP 2020 12:35

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:35	11 SEP 2020 12:35
Nasopharyngeal Swab 2	No		

US3312629

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:16

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐
No ☒

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

PC Time Stamp 11 SEP 2020 13:59

PC Open Date & Time 11 SEP 2020 13:46

PC Close Date & Time 11 SEP 2020 16:16

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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 97.7 °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	11 SEP 2020 18:01
PC Open Date & Time	11 SEP 2020 17:11
PC Close Date & Time	12 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 18:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:49

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

98.3 °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

14 SEP 2020 18:45

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 18:02

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 19:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 19:36

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

11 SEP 2020 13:59

PC Open Date & Time

11 SEP 2020 13:46

PC Close Date & Time

11 SEP 2020 16:16

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

11 SEP 2020 18:02

PC Open Date & Time

11 SEP 2020 17:11

PC Close Date & Time

12 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

12 SEP 2020 18:28

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

13 SEP 2020 19:47

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

14 SEP 2020 18:44

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

15 SEP 2020 18:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

16 SEP 2020 19:51

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

17 SEP 2020 19:35

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 14:00
PC Open Date & Time	11 SEP 2020 13:46
PC Close Date & Time	11 SEP 2020 16:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 18:02
PC Open Date & Time	11 SEP 2020 17:11
PC Close Date & Time	12 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:29
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

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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US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:47
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:44
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

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 ☒

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 19:50
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

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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US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 19:35
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

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)	13 OCT 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:25
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

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)	13 OCT 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 11:45
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 11:14 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 11:14

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

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

10:46 (24 HR)

Collection date and time (derived)

13 OCT 2020 10:46

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:33	13 OCT 2020 10:33
Nasopharyngeal Swab 2	No		

US3312629

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 11:47

PC Open Date & Time

13 OCT 2020 11:34

PC Close Date & Time

13 OCT 2020 14:04

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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	13 OCT 2020 19:39
PC Open Date & Time	13 OCT 2020 14:59
PC Close Date & Time	14 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

96.8 °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

14 OCT 2020 19:42

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 19:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 20:20

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

17 OCT 2020 19:41

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:46

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 20:56

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

13 OCT 2020 11:48

PC Open Date & Time

13 OCT 2020 11:34

PC Close Date & Time

13 OCT 2020 14:04

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 19:37

PC Open Date & Time

13 OCT 2020 14:59

PC Close Date & Time

14 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

14 OCT 2020 19:40

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

15 OCT 2020 19:15

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

16 OCT 2020 20:19

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

17 OCT 2020 19:39

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

18 OCT 2020 19:46

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

19 OCT 2020 20:56

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 11:49
PC Open Date & Time	13 OCT 2020 11:34
PC Close Date & Time	13 OCT 2020 14:04

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 19:36
PC Open Date & Time	13 OCT 2020 14:59
PC Close Date & Time	14 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

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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US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 19:39
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 19:14
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

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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US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 20:18
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

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 ☒

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 19:38
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

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)

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US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:45
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 20:56
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 20 OCT 2020 13:45

PC Open Date & Time 20 OCT 2020 12:00

PC Close Date & Time 21 OCT 2020 11:59

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	20 OCT 2020 13:44
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:04

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 10:45
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312629

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 NOV 2020
Collection time (00:00-23:59)	11:29 (24 HR)
Collection date and time (derived)	16 NOV 2020 11:29

US3312629

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 NOV 2020 04:28:25
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	18 NOV 2020 04:53:08
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 NOV 2020 14:53:12
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 15:27:41
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	06 DEC 2020 16:34:50
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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	13 DEC 2020 05:18:32
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

21 DEC 2020 04:39:51

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 DEC 2020 12:31:13
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

03 JAN 2021 06:06:06

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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	10 JAN 2021 07:46:01
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

17 JAN 2021 07:59:25

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 07:15:56
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

31 JAN 2021 07:50:27

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

07 FEB 2021 06:04:07

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 11:55:09
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 09:28:06
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 12:56:50

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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	07 MAR 2021 13:58:00
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 06:04:52
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

21 MAR 2021 04:19:23

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 04:33:02

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

04 APR 2021 08:57:22

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

11 APR 2021 06:30:49

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

18 APR 2021 04:33:47

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

25 APR 2021 06:10:21

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 05:49:51

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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°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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 <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"/>

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

Patient Cloud Open Date & Time	23 OCT 2022 00:01
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Patient Cloud Close Date & Time	27 OCT 2022 23:59
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US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3312629

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:05:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 15:55:54

US3312629

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:03

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

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

Visit date (dd MMM yyyy)	29 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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US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3312629

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

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.

US3312629

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 MAR 2021
Collection time (00:00-23:59)	10:36 (24 HR)
Collection date and time (derived)	29 MAR 2021 10:36

US3312629

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:17

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 07 Apr 2021 19:38:54

Generated On: 09 Jun 2021 17:05:01

Date of Contact	23 NOV 2020
Time of Contact	09:53
Date and Time of Contact (derived)	23 NOV 2020 09:53
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

Symptom Day

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

Symptom Day

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

Symptom Day

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

Symptom Day

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

Date	24 NOV 2020
------	-------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	97.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

Symptom Day

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

Symptom Day

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

Symptom Day

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

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 24 Apr 2021 14:42:32

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 07 Apr 2021 19:38:54

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 07 Apr 2021 19:38:55

Generated On: 09 Jun 2021 17:05:01

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 07 Apr 2021 19:39:00

Generated On: 09 Jun 2021 17:05:01

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	25 NOV 2020
Day 5	Yes	27 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:00

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:39:00

Generated On: 09 Jun 2021 17:05:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 11:33
Height (xxx.x)	65 in
Weight (xxx.x)	217.8 lb
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)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3312629

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:39:00

Generated On: 09 Jun 2021 17:05:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3312629

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 07 Apr 2021 19:39:00

Generated On: 09 Jun 2021 17:05:01

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

23 NOV 2020

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:38:54

Generated On: 09 Jun 2021 17:05:01

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID SICKD28

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 19:38:54

Generated On: 09 Jun 2021 17:05:01

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:38:26

Generated On: 09 Jun 2021 17:05:01

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.

US3312629

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 07 Apr 2021 19:38:26

Generated On: 09 Jun 2021 17:05:01

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3312629

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

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

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

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

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

Folder OID	UNBLND_DECIDE
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US3312629

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

Form: Unblinding

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

Date of updated informed consent (dd MMM yyyy)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (dd MMM yyyy)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3312629

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3312629

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	22 JAN 2021
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 10:28
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 11:58
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

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

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3312629

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

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

What was the treatment time? (00:00-23:59) 11:27 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 11:27

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

US3312629

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00-23:59)	10:03 (24 HR)
Collection date and time (derived)	22 JAN 2021 10:03

US3312629

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	10:02
Collection Date and Time (derived)	22 JAN 2021 10:02

US3312629

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

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3312629

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

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)	26 FEB 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 11:30
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 FEB 2021
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 12:48
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3312629

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3312629

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 FEB 2021

What was the treatment time? (00:00-23:59) 12:17 (24 HR)

Treatment Date and Time (derived) 26 FEB 2021 12:17

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

US3312629

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:01

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3312629

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 19:39:15

Generated On: 09 Jun 2021 17:05:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312629

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3312629

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3312629

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

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.

US3312629

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3312629

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 16:10:52

Generated On: 09 Jun 2021 17:05:01

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

AEID	USA-US300-2020-MRNA-1273-P30 1000012
Adverse event	SMALL BOWEL OBSTRUCTION
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)	06 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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 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	

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

PER PHONE CALL WITH
SUBJECT 11/09/2020
53 Y/O WOMAN WITH H/O
DIVERTICULOSIS AND PARTIAL
COLECTOMY, SLEEVE
GASTRECTOMY, INCISIONAL
HERNIAS, & HIATAL HERNIA
WHO DEVELOPED ABDOMINAL
PAIN ON 06NOV2020 THAT
RESULTED IN ER VISIT. SMALL
BOWEL OBSTRUCTION WAS
DIAGNOSED; EVAL INCLUDED
CT SCAN AND XRAYS.TREATED
WITH IV FENTANYL AND
TORADOL AND NPO WITHOUT
NG TUBE,HER DIET WAS
ADVANCED TO CLEAR LIQUIDS
BY 08NOV2020. HER CARE
TEAM HOPES TO ADVANCE TO
FULL LIQUIDS TODAY,
09NOV2020. SUBJECT'S PAIN
WAS WELL CONTROLLED AND
SHE WAS IN NO DISTRESS AT
TIME OF PHONE CONTACT
TODAY. SBO BELIEVED TO BE
RELATED TO ADHESIONS
RELATED TO PREVIOUS
PROCEDURES. THIS IS AN SAE
OF SBO, NR TO IP. UPDATE
11NOV2020: SUBJECT
DISCHARGED FROM HOSPITAL
WITHOUT ADDITIONAL
INTERVENTION, HAS HAD
BOWEL MOVEMENTS AND
WITHOUT PAIN. MR

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

PENDING.UPDATE:MEDICAL
RECORDS REVIEWED.SUBJECT
WAS ADMITTED 06NOV2020
WITH PARTIAL SMALL BOWEL
OBSTRUCTION RELATED TO
ADHESIONS FROM HISTORY OF
MULTIPLE ABDOMINAL
SURGERIES.ON DATE OF
ADMISSION DEVELOPED
EPIGASTRIC ABDOMINAL PAIN
AT APPROXIMATELY 12:45 PM
THAT PROGRESSIVELY
WORSENER TO 8 OUT OF 10
SEVERITY OVER HOURS.SELF
INDUCED EMESIS
(NON-BLOODY) DID NOT
RELIEVE PAIN.SHE WENT TO
LOCAL ER WHERE CARE WAS
INITIATED BUT TRANSFERRED
TO ANOTHER SAME
DAY.OVERALL WORK-UP
REVEALED NEGATIVE COVID
TEST 06NOV2020,DILATED
LOOPS OF BOWEL WITHOUT
EVIDENCE OF PNEUMATOSIS
OR ISCHEMIA AND
CONSISTENT WITH PARTIAL
SMALL BOWEL OBSTRUCTION
ON IMAGING, NEUTROPHIL
ELEVATION TO 9000/MICROL
WITHOUT SIGNS OF INFECTION
CONSISTENT WITH STRESS
AND PAIN RELATED
ELEVATION, ABDOMINAL PAIN
THAT RESOLVED WITH IV PAIN

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

MEDS, AND LACTATE LEVEL
OF 3.14 THAT DECREASED TO
1.3 WITH IV
FLUIDS.TREATMENT WAS
CONSERVATIVE WITH NPO,
THEN ADVANCEMENT OF
DIET.ON DAY OF DC 10NOV2020
SUBJECT LOOKED AND FELT
WELL, HAD 2 NORMAL BOWEL
MOVEMENTS, AND A MILD
HYPOKALEMIA OF 3.3 THAT
WAS CORRECTED.AE
RESOLVED

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

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

AEID

Adverse event

LEFT TENNIS ELBOW
(LATERAL EPICONDYLITIS)

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)

15 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

AEID

Adverse event

UPPER RESPIRATORY
INFECTION
(ENTEROVIRUS/RHINOVIRUS)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

AEID

Adverse event

GASTROENTERITIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

AEID

Adverse event

HYPOKALEMIA

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)

10 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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 _____	
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 (7)

Data signed: (b) (4) 07 Apr 2021 19:38:24

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AEID

Adverse event

NORMOCYTIC ANEMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 07 Apr 2021 19:38:26

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	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 (2)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication CURRENT HIATAL HERNIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication MONTELUKAST

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

NIGHTLY

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) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (5)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication AMITRIPYLINE

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

NIGHTLY

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication LORATIDINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	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 (10)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication LIRAGLUTIDE

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	01 JUN 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 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)		08 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication SMALL BOWEL OBSTRUCTION

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 (15)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	06 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)	08 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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication SEASONAL INFLUENZA
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 NOV 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 (17)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication CORTISONE

Prophylaxis Yes ☐
No ☒

Indication LEFT TENNIS ELBOW

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	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	INTRAARTICULAR	
Start date (dd MMM yyyy)	05 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	05 NOV 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 (18)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT TENNIS ELBOW

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY INFECTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication NYQUIL (ACETAMINOPHEN 650
MG - DEXTROMETHORPHAN
HBR 30 MG - DOXYLAMINE
SUCCINATE 12.5 MG

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY INFECTION

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication DOCUSATE

Prophylaxis Yes ☒
No ☐

Indication SMALL BOWEL OBSTRUCTION
PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		2
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication CALCIUM

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
MAINTENANCE

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication VITAMIN B

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	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 2005	
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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication INTRAVENOUS FLUIDS (DEXTROSE/SODIUM CHLORIDE SOLUTION)

Prophylaxis Yes ☐ No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	06 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)	10 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"/>

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

Name of Medication POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 20

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

If dose unit is Other, specify MEQ

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 (27)

Data signed: (b) (4) 07 Apr 2021 19:38:24

Generated On: 09 Jun 2021 17:05:01

	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)		10 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) 10 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"/>

US3312629

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 19:38:26

Generated On: 09 Jun 2021 17:05:01

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3312629

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:05:01

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

US3312629

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:05:01

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 ☐

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	10/NOV/2020 22:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	12/NOV/2020 13:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 07 Apr 2021 19:39:02

Generated On: 09 Jun 2021 17:05:01

SAEID	USA-US300-2020-MRNA-1273-P301000012
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	CARLOS
Investigator's Last Name	FIERRO
Site Address: Street	16300 COLLEGE BLVD
Site Address: City	SHAWNEE
Site Address: State	KS
Site Address: Postal Code	66219
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:58
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

Audit

US3312629 (Prod: Johnson County Clin-Trials)

US3312629

Form: Participant Creation

Generated On: 09 Jun 2021 17:05:01

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'US3312629'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:29:22

US3312629

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User closed query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 20:53:45
Query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed.	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:21
' answered with 'updayed' (Site from DM).		
User opened query 'Per CDM: According to CCGs page 15-16, information is required for Medical History, Vital Signs, Physical Examination, Childbearing potential and Risk of Exposure eCRF forms. Please update as needed. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:41:32
User entered 'Yes (Y)'	Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:28:54

US3312629

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:29:24

US3312629

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[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 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Clinic (Clinic)'	Christa Estrada (b) (4)	11 Sep 2020 18:28:54

US3312629

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'SCRN'	System	11 Sep 2020 18:28:54

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered (b) (6) 1967'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:29:25

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '53'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'YEARS'	System	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '53'	System	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Female (F)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'I'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:05:01

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:12

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Sep 2020'	System	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2020'	System	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Amendment 3 (3)'	Christa Estrada (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:31

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 16:29:24

US3312629

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:05:01

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '1'	System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:05:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:31

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:18
Data point term sent to Coder	System	05 Oct 2020 16:25:35
User entered 'post menopausal'	Karol Moore (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2018'	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2018'	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:24:45

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:17
Data point term sent to Coder	System	05 Oct 2020 16:25:36
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2010'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2010'	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2010'	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:24:56

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:26:18
Data point term sent to Coder	System	05 Oct 2020 16:25:35
User entered 'anxiety'	Karol Moore (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2018'	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2018'	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:06

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:05:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 17:05:22
Data point term sent to Coder	System	05 Oct 2020 16:25:37
User entered 'current hiatal hernia'	Karol Moore (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2016'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2016'	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2016'	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:22

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
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)	05 Oct 2020 16:27:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:27:18
Data point term sent to Coder	System	05 Oct 2020 16:26:39
User entered 'seasonal allergies'	Karol Moore (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2018'	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2018'	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:40

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:27:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:27:19
Data point term sent to Coder	System	05 Oct 2020 16:26:38
User entered 'migraines'	Karol Moore (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2000'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2000'	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2000'	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:25:50

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:43:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:43:23
Data point term sent to Coder	System	05 Oct 2020 16:42:15
User entered 'obesity'	Karol Moore (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un Jan 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 17:17:35
User entered 'No (N)'	Monica Atwood (b) (4)	05 Oct 2020 16:41:27
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	22 Dec 2020 17:17:46
User entered empty; reason for change Data Entry Error	System	22 Dec 2020 17:17:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Monica Atwood (b) (4)	22 Dec 2020 17:17:35
User entered ' Jun 2020' (non-conformant).	(b) (4)	22 Dec 2020 17:17:35
User entered '01 Jun 2020'	Monica Atwood (b) (4)	22 Dec 2020 17:17:35
	(b) (4)	05 Oct 2020 16:41:27
	Karol Moore (b) (4)	
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	22 Dec 2020 17:17:35
User entered 'Jun 2020'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	22 Dec 2020 17:17:35
User entered '2020'	System	05 Oct 2020 16:41:27

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:43:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:43:23
Data point term sent to Coder	System	05 Oct 2020 16:42:18
User entered 'acid reflux'	Karol Moore (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2016'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2016'	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2016'	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:41:55

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastrectomy, LLT: Sleeve gastrectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:44:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:44:27
Data point term sent to Coder	System	05 Oct 2020 16:43:21
User entered 'laparoscopic sleeve gastrectomy'	Karol Moore (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un Jan 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un Jan 2017'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	05 Oct 2020 16:43:07

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:45:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:45:24
Data point term sent to Coder	System	05 Oct 2020 16:44:24
User entered 'diverticulosis'	Karol Moore (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un Jun 2005'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2015'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jun 2005'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2005'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2015'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2015'	System	05 Oct 2020 16:43:48

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Colectomy, LLT: Colectomy partial - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 16:45:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 16:45:25
Data point term sent to Coder	System	05 Oct 2020 16:44:24
User entered 'partial colectomy'	Karol Moore (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un Jun 2015'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	05 Oct 2020 16:45:37
User entered 'UN Jun 2015' reason for change: Data Entry Error	System	05 Oct 2020 16:45:37
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	Karol Moore (b) (4)	05 Oct 2020 16:45:37
User entered 'un UNK 2015'	(b) (4)	05 Oct 2020 16:44:03
	System	05 Oct 2020 16:44:03
	Karol Moore (b) (4)	05 Oct 2020 16:44:03
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jun 2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jun 2015'	System	05 Oct 2020 16:45:37
User entered 'Jan 2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2015'	System	05 Oct 2020 16:44:03

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
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.	Coder Import (b) (4)	05 Oct 2020 16:51:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:33
Data point term sent to Coder	System	05 Oct 2020 16:50:38
User entered 'tramadol allergy'	Karol Moore (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2008'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2008'	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2008'	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:50:11

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 16:51:32
Data point term sent to Coder	System	05 Oct 2020 16:50:38
User entered 'codeine allergy'	Karol Moore (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 1995'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 1995'	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '1995'	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	05 Oct 2020 16:50:23

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 21:01:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 21:01:03
Data point term sent to Coder	System	19 Nov 2020 21:00:25
User entered 'inguinal hernia'	(b) (4), (b) (6)	19 Nov 2020 20:59:41

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Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	19 Nov 2020 20:59:41

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Oesophageal ulcers and perforation, PT: Erosive oesophagitis, LLT: Erosive esophagitis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:47:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:47:03
Data point term sent to Coder	System	16 Feb 2021 21:46:09
User entered 'erosive esophagitis'	(b) (4), (b) (6)	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	16 Feb 2021 21:45:17

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:49:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:49:11
Data point term sent to Coder	System	16 Feb 2021 21:48:15
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2017'	System	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2017'	System	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	16 Feb 2021 21:47:54

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Esophageal irregular z-line - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 21:51:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 21:51:41
Data point term sent to Coder	System	16 Feb 2021 21:53:18
User entered 'irregular z line esophagus'	(b) (4), (b) (6)	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2020'	System	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2020'	System	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	16 Feb 2021 21:52:21

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Duodenal ulcers and perforation, PT: Duodenal ulcer, LLT: Duodenal ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:01:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:01:07
Data point term sent to Coder	System	23 Feb 2021 22:00:20
User entered 'DUODENAL ULCER' reason for change: Data Entry Error	Monica Atwood (b) (4)	23 Feb 2021 21:59:57
Data point term sent to Coder	System	16 Feb 2021 21:54:21
User entered 'h/o duodenal ulcer'	(b) (4), (b) (6)	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:55:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2000' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:55:15
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2000'	System	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2000'	System	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2000'	System	16 Feb 2021 21:55:15
User entered empty.	System	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2000'	System	16 Feb 2021 21:55:15
User entered empty.	System	16 Feb 2021 21:53:29

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:55:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:55:10
Data point term sent to Coder	System	16 Feb 2021 21:54:19
User entered 'sinus infections'	(b) (4), (b) (6)	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:54:56
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	16 Feb 2021 21:54:28
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	16 Feb 2021 21:54:13
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	16 Feb 2021 21:54:56
User entered empty; reason for change Data Entry Error	System	16 Feb 2021 21:54:56
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 21:54:28
User entered 'un UNK 2000' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 21:54:28
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2010'	System	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2010'	System	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	16 Feb 2021 21:54:56
User entered 'Jan 2000'	System	16 Feb 2021 21:54:28
User entered empty.	System	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered empty.	System	16 Feb 2021 21:54:56
User entered '2000'	System	16 Feb 2021 21:54:28
User entered empty.	System	16 Feb 2021 21:54:13

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:34
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'SEE MED HISOTRY LINE 28' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:20:39
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:43:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 21:58:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 21:58:05
Data point term sent to Coder	System	16 Feb 2021 21:57:24
User entered 'Cholecystectomy'	(b) (4), (b) (6)	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	16 Feb 2021 21:57:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 21:57:06
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	16 Feb 2021 21:56:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2001'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2001'	System	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2001'	System	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2001'	System	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2001'	System	16 Feb 2021 21:56:56

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:59:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:59:05
Data point term sent to Coder	System	16 Feb 2021 21:58:25
User entered 'appendectomy'	(b) (4), (b) (6)	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 1981'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 1981'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 1981'	System	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '1981'	System	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 1981'	System	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '1981'	System	16 Feb 2021 21:58:06

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:25:46
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'SEE MED HISTORY LINE 30' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:20:59
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 enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:44:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 22:01:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Feb 2021 22:01:04
Data point term sent to Coder	System	16 Feb 2021 22:00:31
User entered 'Right rotator cuff repair'	(b) (4), (b) (6)	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2011'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2011'	System	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2011'	System	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2011'	System	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2011'	System	16 Feb 2021 21:59:39

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Peripheral nerve decompression, LLT: Ulnar nerve decompression - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 09:44:00
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 09:44:00
Data point term sent to Coder	System	16 Feb 2021 22:07:01
User entered 'Left release of ulnar nerve in guyon's canal'	(b) (4), (b) (6)	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2008'	System	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2008'	System	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2008'	System	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2008'	System	16 Feb 2021 22:06:06

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:07:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:07:40
Data point term sent to Coder	System	16 Feb 2021 22:07:02
User entered 'Right carpal tunnel syndrome'	(b) (4), (b) (6)	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2000'	System	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2000'	System	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2000'	System	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2000'	System	16 Feb 2021 22:06:42

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:08:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:08:44
Data point term sent to Coder	System	16 Feb 2021 22:08:04
User entered 'right carpal tunnel surgery'	(b) (4), (b) (6)	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2000'	System	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2000'	System	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2000'	System	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2000'	System	16 Feb 2021 22:07:14

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:08:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:08:45
Data point term sent to Coder	System	16 Feb 2021 22:08:02
User entered 'Left carpal tunnel syndrome'	(b) (4), (b) (6)	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2005'	System	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2005'	System	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2005'	System	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2005'	System	16 Feb 2021 22:07:43

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:09:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 22:09:41
Data point term sent to Coder	System	16 Feb 2021 22:09:07
User entered 'Left carpal tunnel surgery'	(b) (4), (b) (6)	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2005'	System	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2005'	System	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2005'	System	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2005'	System	16 Feb 2021 22:08:18

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:04:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:04:06
Data point term sent to Coder	System	23 Feb 2021 22:03:36
User entered 'CHOLECYSTITIS'	Monica Atwood (b) (4)	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 2001'	(b) (4) Monica Atwood (b) (4) (b) (4)	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 2001'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2001'	System	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2001'	System	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2001'	System	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (28)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2001'	System	23 Feb 2021 22:02:42

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:04:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:04:05
Data point term sent to Coder	System	23 Feb 2021 22:03:36
User entered 'APPENDICITIS'	Monica Atwood (b) (4)	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 1981'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Monica Atwood (b) (4) (b) (4)	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 1981'	(b) (4) Monica Atwood (b) (4) (b) (4)	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 1981'	System	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '1981'	System	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 1981'	System	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (29)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '1981'	System	23 Feb 2021 22:03:17

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
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 tear - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:05:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Feb 2021 22:05:06
Data point term sent to Coder	System	23 Feb 2021 22:04:37
User entered 'RIGHT ROTATOR CUFF TEAR'	Monica Atwood (b) (4)	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 2011'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'UN UNK 2011'	(b) (4) Monica Atwood (b) (4) (b) (4)	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Monica Atwood (b) (4)	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2011'	System	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2011'	System	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'Jan 2011'	System	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Medical History (30)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '2011'	System	23 Feb 2021 22:04:06

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '12:06'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '11 Sep 2020 12:06'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '65.0' in	(b) (4)	05 Oct 2020 16:51:46
DataPoint set to visible.	Karol Moore (b) (4)	11 Sep 2020 18:29:40
	(b) (4)	
	System	

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '219.4' lb	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46
DataPoint set to visible.	(b) (4) System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered '36.58641'	System	05 Oct 2020 16:51:46
DataPoint set to visible.	System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'kg/m2'	System	05 Oct 2020 16:51:46
DataPoint set to visible.	System	11 Sep 2020 18:29:40

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'bpm'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'breaths/min'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'mmHg'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User entered 'mmHg'	System	05 Oct 2020 16:51:46

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23

US3312629

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23

US3312629

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:52:16

US3312629

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:52:16

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'un UNK 2018'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:05:01

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:53:31

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

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)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '0'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'I'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:05:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:31:23
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'resides in community with ongoing person to person transmission'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:56:00

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Clinic (Clinic)'	(b) (4) Christa Estrada (b) (4) (b) (4)	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'VISIT1'	System	11 Sep 2020 18:29:58

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 17:59:28

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '113445'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 17:59:28

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Sep 2020 17:59:28

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

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)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	Christa Estrada (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

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)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	Christa Estrada (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:13

US3312629

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:05:01

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:56:30
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 06:11:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:11:51

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '12:06'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '11 Sep 2020 12:06'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '97.7' F	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '72'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'bpm'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '14'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'breaths/min'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '113'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '64'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered missing code ND - Not Done.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13:57'	(b) (4)	05 Oct 2020 16:58:08
	Karol Moore (b) (4)	
	(b) (4)	

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '11 Sep 2020 13:57'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '98.2' F	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '79'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'bpm'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '16'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'breaths/min'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '128'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '72'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	05 Oct 2020 16:58:08

US3312629

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 16:59:11

US3312629

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 16:59:11

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

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)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	Christa Estrada (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13:26'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '11 Sep 2020 13:26'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) Christa Estrada (b) (4)	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'ONCE'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 18:30:46

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '12:35'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '11 Sep 2020 12:35'	System	05 Oct 2020 17:02:29

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11 Sep 2020'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '12:35'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '11 Sep 2020 12:35'	System	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered empty.	System	05 Oct 2020 17:02:40

US3312629

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4)	05 Oct 2020 17:02:46
	Karol Moore (b) (4)	
	(b) (4)	

US3312629

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	05 Oct 2020 17:02:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:14', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32'	System	11 Sep 2020 18:59:32
User entered 'Yes (Y)'	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32' User entered '98.2'	System	11 Sep 2020 18:59:32
	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32'	System	11 Sep 2020 18:59:32
User entered 'No (N)'	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0fa2a249-2358-4e3b-95d9-649bd5627b32'	System	11 Sep 2020 18:59:32
User entered '11 Sep 2020 13:59'	System	11 Sep 2020 18:59:32

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 13:46'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 16:16'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:17', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c' User entered 'Yes (Y)'	System	11 Sep 2020 23:01:40
	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c' User entered '97.7'	System	11 Sep 2020 23:01:40
	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c' User entered 'No (N)'	System	11 Sep 2020 23:01:40
	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ab3d3e36-cde4-428f-86ac-80d22e2d7a0c' User entered '11 Sep 2020 18:01'	System	11 Sep 2020 23:01:40
	System	11 Sep 2020 23:01:40

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 17:11'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 2'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3' User entered 'Yes (Y)'	System	12 Sep 2020 23:30:09
	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3' User entered '98.3'	System	12 Sep 2020 23:30:09
	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:30:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3'	System	12 Sep 2020 23:30:09
User entered 'No (N)'	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:30:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '78744b89-16e7-48d1-b2b3-06121cbe04b3'	System	12 Sep 2020 23:30:09
User entered '12 Sep 2020 18:30'	System	12 Sep 2020 23:30:09

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 3'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a'	System	14 Sep 2020 00:49:37
User entered 'Yes (Y)'	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a' User entered '97.8'	System	14 Sep 2020 00:49:37
	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:32', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a'	System	14 Sep 2020 00:49:37
User entered 'No (N)'	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:49:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a7b3d521-450b-414d-9255-496264546a9a'	System	14 Sep 2020 00:49:37
User entered '13 Sep 2020 19:49'	System	14 Sep 2020 00:49:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 4'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:54', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc' User entered 'Yes (Y)'	System	14 Sep 2020 23:45:10
	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc' User entered '98.3'	System	14 Sep 2020 23:45:10
	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:45:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc'	System	14 Sep 2020 23:45:10
User entered 'No (N)'	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:45:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '674f0226-e7d5-4dcf-b370-a223f08a75dc' User entered '14 Sep 2020 18:45'	System	14 Sep 2020 23:45:10
	System	14 Sep 2020 23:45:10

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 5'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370' User entered 'Yes (Y)'	System	15 Sep 2020 23:02:37
	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370' User entered '97.8'	System	15 Sep 2020 23:02:37
	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370' User entered 'No (N)'	System	15 Sep 2020 23:02:37
	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '74bc4a19-0e85-4a5b-aa66-d703e32e6370' User entered '15 Sep 2020 18:02'	System	15 Sep 2020 23:02:37
	System	15 Sep 2020 23:02:37

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 6'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e' User entered 'Yes (Y)'	System	17 Sep 2020 00:51:59
	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e' User entered '97.6'	System	17 Sep 2020 00:51:59
	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:54', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e' User entered 'No (N)'	System	17 Sep 2020 00:51:59
	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b43d5d62-94c5-4b28-ac1b-138af060230e' User entered '16 Sep 2020 19:51'	System	17 Sep 2020 00:51:59
	System	17 Sep 2020 00:51:59

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 7'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32'	System	18 Sep 2020 00:36:39
User entered 'Yes (Y)'	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:36:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32' User entered '98.1'	System	18 Sep 2020 00:36:39
	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:36:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32'	System	18 Sep 2020 00:36:39
User entered 'No (N)'	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:36:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1c856f67-e03c-408b-b60b-d36113e9fb32'	System	18 Sep 2020 00:36:39
User entered '17 Sep 2020 19:36'	System	18 Sep 2020 00:36:39

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db'	System	11 Sep 2020 19:00:06
User entered 'None (1)'	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db' User entered 'No (N)'	System	11 Sep 2020 19:00:06
	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db' User entered 'No (N)'	System	11 Sep 2020 19:00:06
	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db'	System	11 Sep 2020 19:00:06
User entered 'None (1)'	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T13:59:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '04c8aa6c-a75a-472e-bff6-915645aed2db' User entered '11 Sep 2020 13:59'	System	11 Sep 2020 19:00:06
	System	11 Sep 2020 19:00:06

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 13:46'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 16:16'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered 'None (1)'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:01:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered 'No (N)'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7' User entered 'No (N)'	System	11 Sep 2020 23:02:19
	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered 'None (1)'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '441c86ab-b57d-4bc6-9735-7018502e71e7'	System	11 Sep 2020 23:02:19
User entered '11 Sep 2020 18:02'	System	11 Sep 2020 23:02:19

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 17:11'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 2'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered 'None (1)'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered 'No (N)'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9' User entered 'No (N)'	System	12 Sep 2020 23:28:57
	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered 'None (1)'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:28:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e34a5b2d-e9f8-4aca-ae3f-62d9161b60b9'	System	12 Sep 2020 23:28:57
User entered '12 Sep 2020 18:28'	System	12 Sep 2020 23:28:57

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 3'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:46:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c' User entered 'None (1)'	System	14 Sep 2020 00:47:09
	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:46:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c' User entered 'No (N)'	System	14 Sep 2020 00:47:09
	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:46:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c' User entered 'No (N)'	System	14 Sep 2020 00:47:09
	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c' User entered 'None (1)'	System	14 Sep 2020 00:47:09
	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:05', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'eadc562a-07eb-4e6a-9c05-fce8858a6b8c' User entered '13 Sep 2020 19:47'	System	14 Sep 2020 00:47:09
	System	14 Sep 2020 00:47:09

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 4'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:43:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'None (1)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:43:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'No (N)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'No (N)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered 'None (1)'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b2deec9e-b805-4406-8de8-bd52009bb588'	System	14 Sep 2020 23:44:22
User entered '14 Sep 2020 18:44'	System	14 Sep 2020 23:44:22

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 5'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'None (1)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'No (N)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:31', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'No (N)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered 'None (1)'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2129d901-141a-4d22-8665-43a79c6cbd16'	System	15 Sep 2020 23:01:43
User entered '15 Sep 2020 18:01'	System	15 Sep 2020 23:01:43

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 6'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049' User entered 'None (1)'	System	17 Sep 2020 00:51:32
	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049' User entered 'No (N)'	System	17 Sep 2020 00:51:32
	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049' User entered 'No (N)'	System	17 Sep 2020 00:51:32
	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049' User entered 'None (1)'	System	17 Sep 2020 00:51:32
	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:51:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5c16239e-49ec-4b97-b39a-1a686006e049' User entered '16 Sep 2020 19:51'	System	17 Sep 2020 00:51:32
	System	17 Sep 2020 00:51:32

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 7'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269'	System	18 Sep 2020 00:35:42
User entered 'None (1)'	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269' User entered 'No (N)'	System	18 Sep 2020 00:35:42
	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269' User entered 'No (N)'	System	18 Sep 2020 00:35:42
	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269'	System	18 Sep 2020 00:35:42
User entered 'None (1)'	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:38', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aca11689-6040-442a-8b6c-c048f9efa269' User entered '17 Sep 2020 19:35'	System	18 Sep 2020 00:35:42
	System	18 Sep 2020 00:35:42

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'None (0)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:08', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87' User entered 'None (0)'	System	11 Sep 2020 19:00:26
	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:11', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87' User entered 'None (0)'	System	11 Sep 2020 19:00:26
	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87' User entered 'None (0)'	System	11 Sep 2020 19:00:26
	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87' User entered 'None (0)'	System	11 Sep 2020 19:00:26
	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:17', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87' User entered 'None (0)'	System	11 Sep 2020 19:00:26
	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:20', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered 'No (N)'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T14:00:23', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1167e38a-b82a-4492-a91b-4d7b41d27e87'	System	11 Sep 2020 19:00:26
User entered '11 Sep 2020 14:00'	System	11 Sep 2020 19:00:26

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 13:46'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 16:16'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered 'None (0)'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:26', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered 'None (0)'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered 'None (0)'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered 'None (0)'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:35', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered 'None (0)'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered 'None (0)'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928' User entered 'No (N)'	System	11 Sep 2020 23:03:16
	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-11T18:02:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'f18ade49-d08c-44ef-a392-a28eb0119928'	System	11 Sep 2020 23:03:16
User entered '11 Sep 2020 18:02'	System	11 Sep 2020 23:03:16

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '11 Sep 2020 17:11'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 2'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered 'None (0)'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered 'None (0)'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:09', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered 'None (0)'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered 'None (0)'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered 'None (0)'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:20', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered 'None (0)'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered 'No (N)'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-12T18:29:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac87933b-2ecf-40eb-a885-d4800abbaae7' User entered '12 Sep 2020 18:29'	System	12 Sep 2020 23:29:30
	System	12 Sep 2020 23:29:30

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 3'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered 'None (0)'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered 'None (0)'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:21', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered 'None (0)'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:26', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered 'None (0)'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered 'None (0)'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered 'None (0)'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered 'No (N)'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-13T19:47:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b2069d2-ba8a-425b-bd18-eb9ed1c1478f' User entered '13 Sep 2020 19:47'	System	14 Sep 2020 00:47:46
	System	14 Sep 2020 00:47:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 4'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered 'None (0)'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered 'None (0)'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered 'None (0)'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered 'None (0)'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered 'None (0)'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered 'None (0)'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered 'No (N)'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-14T18:44:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6f9593c2-18d7-4ca6-94f0-bf16c710d3c1' User entered '14 Sep 2020 18:44'	System	14 Sep 2020 23:44:52
	System	14 Sep 2020 23:44:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 5'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7' User entered 'None (0)'	System	15 Sep 2020 23:02:08
	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'None (0)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7' User entered 'None (0)'	System	15 Sep 2020 23:02:08
	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7' User entered 'None (0)'	System	15 Sep 2020 23:02:08
	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:01:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7' User entered 'None (0)'	System	15 Sep 2020 23:02:08
	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered 'No (N)'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-15T18:02:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b1ed2dfa-5b79-4928-986a-739ddf3ed1f7'	System	15 Sep 2020 23:02:08
User entered '15 Sep 2020 18:02'	System	15 Sep 2020 23:02:08

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 6'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:31', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307' User entered 'None (0)'	System	17 Sep 2020 00:50:52
	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'None (0)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered 'No (N)'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-16T19:50:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b3217adc-8416-4a61-9f16-7fd2f728f307'	System	17 Sep 2020 00:50:52
User entered '16 Sep 2020 19:50'	System	17 Sep 2020 00:50:52

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 7'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:34:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996' User entered 'None (0)'	System	18 Sep 2020 00:35:22
	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'None (0)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered 'No (N)'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-09-17T19:35:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'fadd7dff-e414-417d-8c0e-f203d8797996'	System	18 Sep 2020 00:35:22
User entered '17 Sep 2020 19:35'	System	18 Sep 2020 00:35:22

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:30:46

US3312629

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:03:09

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '18 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:03:09

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:03:09

US3312629

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4)	05 Oct 2020 17:03:09
	Karol Moore (b) (4)	
	(b) (4)	

US3312629

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:03:24

US3312629

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	05 Oct 2020 17:03:24

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:04:07

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '25 Sep 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:07

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:07

US3312629

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:04:07
	(b) (4)	

US3312629

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:04:10

US3312629

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	05 Oct 2020 17:04:10

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '02 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:04:29

US3312629

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	05 Oct 2020 17:04:32

US3312629

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	05 Oct 2020 17:04:32

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'VISIT2'	System	13 Oct 2020 16:25:39

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Pre-Dose (PREDOSE)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '10:25'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '13 Oct 2020 10:25'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '98.5' F	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '74'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'bpm'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '16'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'breaths/min'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '114'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '70'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Post-Dose (POSTDOSE)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13 Oct 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11:45'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '13 Oct 2020 11:45'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '98.1' F	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '73'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'bpm'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '16'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'breaths/min'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '112'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '74'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	15 Oct 2020 16:24:33

US3312629

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:46

US3312629

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13 Oct 2020'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:24:46

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

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)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11:14'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '13 Oct 2020 11:14'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'ONCE'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 16:25:58

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:25:01

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13 Oct 2020'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:25:01
	(b) (4)	

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '10:46'	(b) (4) Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:01

US3312629

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '13 Oct 2020 10:46'	System	15 Oct 2020 16:25:01

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:05:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '13 Oct 2020'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '10:33'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '13 Oct 2020 10:33'	System	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karol Moore (b) (4) (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) Karol Moore (b) (4)	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered empty.	System	15 Oct 2020 16:25:16

US3312629

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:26:05

US3312629

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	13 Oct 2020 16:26:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086' User entered 'Yes (Y)'	System	13 Oct 2020 16:47:44
	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086' User entered '98.1'	System	13 Oct 2020 16:47:44
	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086' User entered 'No (N)'	System	13 Oct 2020 16:47:44
	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac0913bd-8645-4a74-bf8b-8d55106a9086' User entered '13 Oct 2020 11:47'	System	13 Oct 2020 16:47:44
	System	13 Oct 2020 16:47:44

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 11:34'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 14:04'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:38', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c' User entered 'Yes (Y)'	System	14 Oct 2020 00:39:52
	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:39:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c' User entered '97.9'	System	14 Oct 2020 00:39:52
	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:39:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c'	System	14 Oct 2020 00:39:52
User entered 'No (N)'	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:39:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '3382d5c8-403a-410a-81fd-29a87df8ec8c' User entered '13 Oct 2020 19:39'	System	14 Oct 2020 00:39:52
	System	14 Oct 2020 00:39:52

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 14:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 2'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:41:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249'	System	15 Oct 2020 00:42:30
User entered 'Yes (Y)'	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:42:20', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249'	System	15 Oct 2020 00:42:30
User entered '96.8'	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:42:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249'	System	15 Oct 2020 00:42:30
User entered 'No (N)'	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:42:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'db187be3-f717-4069-ae56-49c1c5cef249' User entered '14 Oct 2020 19:42'	System	15 Oct 2020 00:42:30
	System	15 Oct 2020 00:42:30

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 3'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b' User entered 'Yes (Y)'	System	16 Oct 2020 00:16:05
	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b' User entered '97.3'	System	16 Oct 2020 00:16:05
	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b' User entered 'No (N)'	System	16 Oct 2020 00:16:05
	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:16:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2b876256-52e9-46c4-a551-acd3e827e00b' User entered '15 Oct 2020 19:16'	System	16 Oct 2020 00:16:05
	System	16 Oct 2020 00:16:05

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 4'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:19:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e' User entered 'Yes (Y)'	System	17 Oct 2020 01:21:12
	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:20:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e' User entered '97.4'	System	17 Oct 2020 01:21:12
	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:20:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e' User entered 'No (N)'	System	17 Oct 2020 01:21:12
	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:20:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1b7ea2ca-c8a1-43b7-8775-31aaa180478e' User entered '16 Oct 2020 20:20'	System	17 Oct 2020 01:21:12
	System	17 Oct 2020 01:21:12

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 5'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:39:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74' User entered 'Yes (Y)'	System	18 Oct 2020 00:41:09
	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:41:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74' User entered '97.8'	System	18 Oct 2020 00:41:09
	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:41:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74'	System	18 Oct 2020 00:41:09
User entered 'No (N)'	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:41:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '047475bc-1917-4251-8847-0aa0bb0c7f74' User entered '17 Oct 2020 19:41'	System	18 Oct 2020 00:41:09
	System	18 Oct 2020 00:41:09

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 6'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573' User entered 'Yes (Y)'	System	19 Oct 2020 00:46:56
	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573' User entered '98.2'	System	19 Oct 2020 00:46:56
	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573'	System	19 Oct 2020 00:46:56
User entered 'No (N)'	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:54', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '454c7c1b-7601-4566-bce6-4fa771662573'	System	19 Oct 2020 00:46:56
User entered '18 Oct 2020 19:46'	System	19 Oct 2020 00:46:56

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 7'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125' User entered 'Yes (Y)'	System	20 Oct 2020 01:56:55
	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125' User entered '98.2'	System	20 Oct 2020 01:56:55
	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125'	System	20 Oct 2020 01:56:55
User entered 'No (N)'	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5e0b9fd7-c7c7-45ba-aa61-e4174964e125' User entered '19 Oct 2020 20:56'	System	20 Oct 2020 01:56:55
	System	20 Oct 2020 01:56:55

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde' User entered 'None (1)'	System	13 Oct 2020 16:48:11
	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:50', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde' User entered 'No (N)'	System	13 Oct 2020 16:48:11
	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:47:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde' User entered 'No (N)'	System	13 Oct 2020 16:48:11
	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde' User entered 'None (1)'	System	13 Oct 2020 16:48:11
	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '611aeb4d-d277-4c04-af5f-107132251bde' User entered '13 Oct 2020 11:48'	System	13 Oct 2020 16:48:11
	System	13 Oct 2020 16:48:11

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 11:34'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 14:04'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165'	System	14 Oct 2020 00:37:14
User entered 'None (1)'	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165' User entered 'No (N)'	System	14 Oct 2020 00:37:14
	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165' User entered 'No (N)'	System	14 Oct 2020 00:37:14
	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165' User entered 'None (1)'	System	14 Oct 2020 00:37:14
	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:37:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '86580dea-0f0b-4e6f-bee4-b6ecbbb98165' User entered '13 Oct 2020 19:37'	System	14 Oct 2020 00:37:14
	System	14 Oct 2020 00:37:14

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 14:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 2'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd'	System	15 Oct 2020 00:40:18
User entered 'None (1)'	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd' User entered 'No (N)'	System	15 Oct 2020 00:40:18
	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:40:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd'	System	15 Oct 2020 00:40:18
User entered 'No (N)'	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:40:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd'	System	15 Oct 2020 00:40:18
User entered 'None (1)'	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:40:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '249c25f9-be90-4414-a906-34f82326fefd'	System	15 Oct 2020 00:40:18
User entered '14 Oct 2020 19:40'	System	15 Oct 2020 00:40:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 3'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad'	System	16 Oct 2020 00:15:38
User entered 'None (1)'	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:05', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad' User entered 'No (N)'	System	16 Oct 2020 00:15:38
	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad' User entered 'No (N)'	System	16 Oct 2020 00:15:38
	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad'	System	16 Oct 2020 00:15:38
User entered 'None (1)'	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:15:35', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2dbd8c56-0026-4b06-8c86-ac8939d319ad' User entered '15 Oct 2020 19:15'	System	16 Oct 2020 00:15:38
	System	16 Oct 2020 00:15:38

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 4'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered 'None (1)'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered 'No (N)'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333' User entered 'No (N)'	System	17 Oct 2020 01:19:12
	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:19:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered 'None (1)'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:19:05', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '5ed8b36a-d4b5-4e2d-aaf6-0fd7df9ff333'	System	17 Oct 2020 01:19:12
User entered '16 Oct 2020 20:19'	System	17 Oct 2020 01:19:12

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 5'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d' User entered 'None (1)'	System	18 Oct 2020 00:39:18
	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d' User entered 'No (N)'	System	18 Oct 2020 00:39:18
	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d' User entered 'No (N)'	System	18 Oct 2020 00:39:18
	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:39:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d' User entered 'None (1)'	System	18 Oct 2020 00:39:18
	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:39:14', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '33ecd041-590e-4a90-b9a5-3d36a95cb43d' User entered '17 Oct 2020 19:39'	System	18 Oct 2020 00:39:18
	System	18 Oct 2020 00:39:18

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 6'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb' User entered 'None (1)'	System	19 Oct 2020 00:46:13
	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb' User entered 'No (N)'	System	19 Oct 2020 00:46:13
	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb' User entered 'No (N)'	System	19 Oct 2020 00:46:13
	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:08', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb' User entered 'None (1)'	System	19 Oct 2020 00:46:13
	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:46:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '092b9fbd-8ac4-41f5-8328-388ba2a061cb' User entered '18 Oct 2020 19:46'	System	19 Oct 2020 00:46:13
	System	19 Oct 2020 00:46:13

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 7'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31'	System	20 Oct 2020 01:56:39
User entered 'None (1)'	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:18', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31' User entered 'No (N)'	System	20 Oct 2020 01:56:39
	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:23', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31' User entered 'No (N)'	System	20 Oct 2020 01:56:39
	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31' User entered 'None (1)'	System	20 Oct 2020 01:56:39
	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'abedd8ad-c866-47c2-a717-8d5d6f391c31' User entered '19 Oct 2020 20:56'	System	20 Oct 2020 01:56:39
	System	20 Oct 2020 01:56:39

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered 'None (0)'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered 'None (0)'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered 'None (0)'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered 'None (0)'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered 'None (0)'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered 'None (0)'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:48:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered 'No (N)'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T11:49:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '87fc4269-f9f7-4db3-a959-e89ef9177870' User entered '13 Oct 2020 11:49'	System	13 Oct 2020 16:49:07
	System	13 Oct 2020 16:49:07

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 11:34'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 14:04'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:11', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered 'None (0)'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered 'None (0)'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered 'None (0)'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered 'None (0)'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:34', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered 'None (0)'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered 'None (0)'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered 'No (N)'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-13T19:36:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '50403aa7-9692-4a0f-b116-ebe0cd0ae2d0' User entered '13 Oct 2020 19:36'	System	14 Oct 2020 00:36:50
	System	14 Oct 2020 00:36:50

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '13 Oct 2020 14:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 2'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:29', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered 'None (0)'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:32', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered 'None (0)'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:36', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered 'None (0)'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered 'None (0)'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered 'None (0)'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered 'None (0)'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered 'No (N)'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-14T19:39:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '22a3d11a-7d4f-4186-9970-cb323039f050' User entered '14 Oct 2020 19:39'	System	15 Oct 2020 00:39:56
	System	15 Oct 2020 00:39:56

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 3'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:48', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'None (0)'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered 'No (N)'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-15T19:14:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'ac63c6f0-9fcf-459b-9d1c-1ada103c7859' User entered '15 Oct 2020 19:14'	System	16 Oct 2020 00:15:03
	System	16 Oct 2020 00:15:03

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 4'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'None (0)'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:09', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'None (0)'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:11', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'None (0)'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:14', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'None (0)'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:16', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'None (0)'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:23', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'None (0)'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:30', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered 'No (N)'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-16T20:18:32', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4898dc4d-fb0d-4ca6-a3b2-d77e1ea9c441' User entered '16 Oct 2020 20:18'	System	17 Oct 2020 01:18:37
	System	17 Oct 2020 01:18:37

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 5'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:33', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:40', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:44', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:50', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:37:53', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'None (0)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered 'No (N)'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-17T19:38:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '795ff370-6c89-44a9-913b-d8e595cf1a66'	System	18 Oct 2020 00:38:09
User entered '17 Oct 2020 19:38'	System	18 Oct 2020 00:38:09

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 6'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered 'None (0)'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered 'None (0)'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:31', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered 'None (0)'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:35', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered 'None (0)'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered 'None (0)'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered 'None (0)'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:43', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered 'No (N)'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-18T19:45:46', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '554d86a2-6c8d-4c29-8e6e-68fa0919cc70' User entered '18 Oct 2020 19:45'	System	19 Oct 2020 00:45:48
	System	19 Oct 2020 00:45:48

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	13 Oct 2020 16:25:58
User entered 'Day 7'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'None (0)'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:39', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'None (0)'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'None (0)'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:55:45', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'None (0)'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd'	System	20 Oct 2020 01:56:13
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'None (0)'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered 'No (N)'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-19T20:56:10', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6637cd6c-7c94-49b3-a151-17f1718eeacd' User entered '19 Oct 2020 20:56'	System	20 Oct 2020 01:56:13
	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 16:25:58

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	20 Oct 2020 01:56:13
User entered 'Day 8'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:05:01

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:44:59', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e4cc8f67-caa1-42a4-b750-16b82f2953a5' User entered 'None (0)'	System	20 Oct 2020 18:45:07
	System	20 Oct 2020 18:45:07

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:45:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e4cc8f67-caa1-42a4-b750-16b82f2953a5' User entered '20 Oct 2020 13:45'	System	20 Oct 2020 18:45:07
	System	20 Oct 2020 18:45:07

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	20 Oct 2020 01:56:13
User entered 'Day 8'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:44:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '96154570-9b23-4ec9-a74b-6b1b91fea85f' User entered 'No (N)'	System	20 Oct 2020 18:44:55
	System	20 Oct 2020 18:44:55

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-10-20T13:44:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '96154570-9b23-4ec9-a74b-6b1b91fea85f' User entered '20 Oct 2020 13:44'	System	20 Oct 2020 18:44:55
	System	20 Oct 2020 18:44:55

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '20 Oct 2020 12:00'	System	20 Oct 2020 01:56:13

US3312629

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:05:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
User entered '21 Oct 2020 11:59'	System	20 Oct 2020 01:56:13

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:32:34

US3312629

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:32:40

US3312629

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	21 Oct 2020 19:32:40

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:18:57

US3312629

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:19:05

US3312629

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	28 Oct 2020 17:19:05

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:44

US3312629

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:33:28

US3312629

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	04 Nov 2020 15:33:28

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'VISIT3'	System	19 Nov 2020 20:50:23

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '10:45'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '16 Nov 2020 10:45'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '69'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'bpm'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'breaths/min'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '121'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '73'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'mmHg'	System	19 Nov 2020 20:50:43

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48

US3312629

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48

US3312629

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:52

US3312629

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:50:52

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '11:29'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '16 Nov 2020 11:29'	System	19 Nov 2020 20:51:04

US3312629

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:51:09

US3312629

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered '1'	System	19 Nov 2020 20:51:09

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 64'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-11T04:28:15', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '14dd6fc3-97c9-43ad-a8bc-b7076896c848'	System	11 Nov 2020 10:28:27
User entered 'No (N)'	System	11 Nov 2020 10:28:27

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-11T04:27:19', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '14dd6fc3-97c9-43ad-a8bc-b7076896c848'	System	11 Nov 2020 10:28:27
User entered 'No (N)'	System	11 Nov 2020 10:28:27

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-11T04:28:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '14dd6fc3-97c9-43ad-a8bc-b7076896c848' User entered '11 Nov 2020 04:28:25'	System	11 Nov 2020 10:28:27
	System	11 Nov 2020 10:28:27

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered 'Day 71'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-18T04:52:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '42eb7e57-decd-40a9-94ff-92e1b0b5aec0'	System	18 Nov 2020 10:53:10
User entered 'No (N)'	System	18 Nov 2020 10:53:10

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-18T04:53:04', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '42eb7e57-decd-40a9-94ff-92e1b0b5aec0'	System	18 Nov 2020 10:53:10
User entered 'No (N)'	System	18 Nov 2020 10:53:10

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-18T04:53:08', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '42eb7e57-decd-40a9-94ff-92e1b0b5aec0' User entered '18 Nov 2020 04:53:08'	System	18 Nov 2020 10:53:10
	System	18 Nov 2020 10:53:10

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 18:30:46

US3312629

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:30:31
Data entry locked.	System	11 Sep 2020 18:30:46
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 18:30:46

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered 'Yes (Y)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered 'No (N)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:22', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered 'Yes (Y)'	System	22 Nov 2020 20:53:24
	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '0'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:52:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349' User entered '1'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Please 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:53:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:53:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-aee3-d24bbfd11349'	System	22 Nov 2020 20:53:24
User entered 'No (N)'	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-22T14:53:12', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0ae54694-cc5a-4287-ae3-d24bbfd11349' User entered '22 Nov 2020 14:53:12'	System	22 Nov 2020 20:53:24
	System	22 Nov 2020 20:53:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-29T15:27:31', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a797e22c-a5f1-4c1e-ab2e-e38726286c3d' User entered 'No (N)'	System	29 Nov 2020 21:27:47
	System	29 Nov 2020 21:27:47

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-29T15:27:37', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a797e22c-a5f1-4c1e-ab2e-e38726286c3d' User entered 'No (N)'	System	29 Nov 2020 21:27:47
	System	29 Nov 2020 21:27:47

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-11-29T15:27:41', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'a797e22c-a5f1-4c1e-ab2e-e38726286c3d' User entered '29 Nov 2020 15:27:41'	System	29 Nov 2020 21:27:47
	System	29 Nov 2020 21:27:47

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-06T16:34:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e376ab4a-549d-4d21-a911-e74269390ad3'	System	06 Dec 2020 22:34:52
User entered 'No (N)'	System	06 Dec 2020 22:34:52

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-06T16:34:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e376ab4a-549d-4d21-a911-e74269390ad3'	System	06 Dec 2020 22:34:52
User entered 'No (N)'	System	06 Dec 2020 22:34:52

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-06T16:34:50', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e376ab4a-549d-4d21-a911-e74269390ad3' User entered '06 Dec 2020 16:34:50'	System	06 Dec 2020 22:34:52
	System	06 Dec 2020 22:34:52

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-13T05:18:21', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '8459ecfd-8030-43cd-907f-b8b89542243b' User entered 'No (N)'	System	13 Dec 2020 11:18:35
	System	13 Dec 2020 11:18:35

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-13T05:18:28', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '8459ecfd-8030-43cd-907f-b8b89542243b' User entered 'No (N)'	System	13 Dec 2020 11:18:35
	System	13 Dec 2020 11:18:35

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-13T05:18:32', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '8459ecfd-8030-43cd-907f-b8b89542243b' User entered '13 Dec 2020 05:18:32'	System	13 Dec 2020 11:18:35
	System	13 Dec 2020 11:18:35

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-21T04:39:42', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '818770b6-e051-49b6-868c-c93f88112864' User entered 'No (N)'	System	21 Dec 2020 10:39:54
	System	21 Dec 2020 10:39:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-21T04:39:47', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '818770b6-e051-49b6-868c-c93f88112864' User entered 'No (N)'	System	21 Dec 2020 10:39:54
	System	21 Dec 2020 10:39:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-21T04:39:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '818770b6-e051-49b6-868c-c93f88112864' User entered '21 Dec 2020 04:39:51'	System	21 Dec 2020 10:39:54
	System	21 Dec 2020 10:39:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-27T12:30:55', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6163f6ed-1112-46b6-9483-e6d5a70ecca4' User entered 'No (N)'	System	27 Dec 2020 18:31:16
	System	27 Dec 2020 18:31:16

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-27T12:31:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6163f6ed-1112-46b6-9483-e6d5a70ecca4' User entered 'No (N)'	System	27 Dec 2020 18:31:16
	System	27 Dec 2020 18:31:16

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2020-12-27T12:31:13', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6163f6ed-1112-46b6-9483-e6d5a70ecca4' User entered '27 Dec 2020 12:31:13'	System	27 Dec 2020 18:31:16
	System	27 Dec 2020 18:31:16

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-03T06:05:54', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e7558521-8a8f-406f-8177-5d7dcfdf4645'	System	03 Jan 2021 12:06:12
User entered 'No (N)'	System	03 Jan 2021 12:06:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-03T06:06:03', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e7558521-8a8f-406f-8177-5d7dcfdf4645'	System	03 Jan 2021 12:06:12
User entered 'No (N)'	System	03 Jan 2021 12:06:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-03T06:06:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e7558521-8a8f-406f-8177-5d7dcfdf4645' User entered '03 Jan 2021 06:06:06'	System	03 Jan 2021 12:06:12
	System	03 Jan 2021 12:06:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-10T07:45:51', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1f95c562-1a3e-4d73-b3e9-78d7a0f0ee69'	System	10 Jan 2021 13:46:05
User entered 'No (N)'	System	10 Jan 2021 13:46:05

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-10T07:45:57', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1f95c562-1a3e-4d73-b3e9-78d7a0f0ee69'	System	10 Jan 2021 13:46:05
User entered 'No (N)'	System	10 Jan 2021 13:46:05

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-10T07:46:01', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '1f95c562-1a3e-4d73-b3e9-78d7a0f0ee69' User entered '10 Jan 2021 07:46:01'	System	10 Jan 2021 13:46:05
	System	10 Jan 2021 13:46:05

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-17T07:59:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '20cdde99-e4da-4891-8c94-ddd1f56edbe5'	System	17 Jan 2021 13:59:27
User entered 'No (N)'	System	17 Jan 2021 13:59:27

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-17T07:59:11', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '20cdde99-e4da-4891-8c94-ddd1f56edbe5'	System	17 Jan 2021 13:59:27
User entered 'No (N)'	System	17 Jan 2021 13:59:27

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-17T07:59:25', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '20cdde99-e4da-4891-8c94-ddd1f56edbe5' User entered '17 Jan 2021 07:59:25'	System	17 Jan 2021 13:59:27

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-24T07:15:49', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2d3f80da-9bba-4577-8772-dd65df127acf' User entered 'No (N)'	System	24 Jan 2021 13:15:58
	System	24 Jan 2021 13:15:58

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-24T07:15:52', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2d3f80da-9bba-4577-8772-dd65df127acf'	System	24 Jan 2021 13:15:58
User entered 'No (N)'	System	24 Jan 2021 13:15:58

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-24T07:15:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '2d3f80da-9bba-4577-8772-dd65df127acf' User entered '24 Jan 2021 07:15:56'	System	24 Jan 2021 13:15:58
	System	24 Jan 2021 13:15:58

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-31T07:50:21', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e76d1b33-7ee9-4f64-a3f0-e450721f5696'	System	31 Jan 2021 13:50:30
User entered 'No (N)'	System	31 Jan 2021 13:50:30

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-31T07:50:24', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e76d1b33-7ee9-4f64-a3f0-e450721f5696' User entered 'No (N)'	System	31 Jan 2021 13:50:30

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-01-31T07:50:27', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'e76d1b33-7ee9-4f64-a3f0-e450721f5696' User entered '31 Jan 2021 07:50:27'	System	31 Jan 2021 13:50:30
	System	31 Jan 2021 13:50:30

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-07T06:03:56', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '31754cd6-3b48-4248-a019-f91cea74d31a' User entered 'No (N)'	System	07 Feb 2021 12:04:12
	System	07 Feb 2021 12:04:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-07T06:04:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '31754cd6-3b48-4248-a019-f91cea74d31a' User entered 'No (N)'	System	07 Feb 2021 12:04:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-07T06:04:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '31754cd6-3b48-4248-a019-f91cea74d31a' User entered '07 Feb 2021 06:04:07'	System	07 Feb 2021 12:04:12
	System	07 Feb 2021 12:04:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-14T11:54:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'c8f08168-914c-4d77-bf81-4e89b20f1eb9' User entered 'No (N)'	System	14 Feb 2021 17:55:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-14T11:55:07', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'c8f08168-914c-4d77-bf81-4e89b20f1eb9'	System	14 Feb 2021 17:55:12
User entered 'No (N)'	System	14 Feb 2021 17:55:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-14T11:55:09', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'c8f08168-914c-4d77-bf81-4e89b20f1eb9' User entered '14 Feb 2021 11:55:09'	System	14 Feb 2021 17:55:12
	System	14 Feb 2021 17:55:12

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-21T09:27:58', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'c93456a4-b23e-4180-ac35-1c31c1f608dd' User entered 'No (N)'	System	21 Feb 2021 15:28:11

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-21T09:28:02', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'c93456a4-b23e-4180-ac35-1c31c1f608dd' User entered 'No (N)'	System	21 Feb 2021 15:28:11

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-21T09:28:06', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'c93456a4-b23e-4180-ac35-1c31c1f608dd' User entered '21 Feb 2021 09:28:06'	System	21 Feb 2021 15:28:11
	System	21 Feb 2021 15:28:11

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-28T06:56:43-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6d63a78f-76a0-4d06-9817-2b4f065c80c7'	System	28 Feb 2021 12:56:55
User entered 'No (N)'	System	28 Feb 2021 12:56:55

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-28T06:56:46-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6d63a78f-76a0-4d06-9817-2b4f065c80c7'	System	28 Feb 2021 12:56:55
User entered 'No (N)'	System	28 Feb 2021 12:56:55

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-28T06:56:50-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '6d63a78f-76a0-4d06-9817-2b4f065c80c7' User entered '28 Feb 2021 12:56:50'	System	28 Feb 2021 12:56:55
	System	28 Feb 2021 12:56:55

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-07T07:57:54-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '06d118f3-dc99-4f45-bbe7-cea9100a19bb'	System	07 Mar 2021 13:58:02
User entered 'No (N)'	System	07 Mar 2021 13:58:02

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-07T07:57:57-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '06d118f3-dc99-4f45-bbe7-cea9100a19bb'	System	07 Mar 2021 13:58:02
User entered 'No (N)'	System	07 Mar 2021 13:58:02

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-07T07:58:00-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '06d118f3-dc99-4f45-bbe7-cea9100a19bb'	System	07 Mar 2021 13:58:02
User entered '07 Mar 2021 13:58:00'	System	07 Mar 2021 13:58:02

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-14T06:04:39-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '536f6ba8-15d3-492c-b276-1f9822ecf3cf'	System	14 Mar 2021 11:04:54
User entered 'No (N)'	System	14 Mar 2021 11:04:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-14T06:04:48-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '536f6ba8-15d3-492c-b276-1f9822ecf3cf' User entered 'No (N)'	System	14 Mar 2021 11:04:54
	System	14 Mar 2021 11:04:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-14T06:04:52-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '536f6ba8-15d3-492c-b276-1f9822ecf3cf' User entered '14 Mar 2021 06:04:52'	System	14 Mar 2021 11:04:54
	System	14 Mar 2021 11:04:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-21T04:19:14-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '543bd456-327b-4123-a492-cb174772a7de'	System	21 Mar 2021 09:19:26
User entered 'No (N)'	System	21 Mar 2021 09:19:26

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-21T04:19:20-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '543bd456-327b-4123-a492-cb174772a7de'	System	21 Mar 2021 09:19:26
User entered 'No (N)'	System	21 Mar 2021 09:19:26

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-21T04:19:23-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '543bd456-327b-4123-a492-cb174772a7de'	System	21 Mar 2021 09:19:26
User entered '21 Mar 2021 04:19:23'	System	21 Mar 2021 09:19:26

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-28T04:32:51-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '15e6e289-9995-4f21-ab82-2337c2b0def5'	System	28 Mar 2021 09:33:06
User entered 'No (N)'	System	28 Mar 2021 09:33:06

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-28T04:32:59-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '15e6e289-9995-4f21-ab82-2337c2b0def5'	System	28 Mar 2021 09:33:06
User entered 'No (N)'	System	28 Mar 2021 09:33:06

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-03-28T04:33:02-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '15e6e289-9995-4f21-ab82-2337c2b0def5' User entered '28 Mar 2021 04:33:02'	System	28 Mar 2021 09:33:06
	System	28 Mar 2021 09:33:06

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-04T08:57:15-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aae4f16c-f493-42a7-9620-985138fad846'	System	04 Apr 2021 13:57:24
User entered 'No (N)'	System	04 Apr 2021 13:57:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-04T08:57:19-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aae4f16c-f493-42a7-9620-985138fad846'	System	04 Apr 2021 13:57:24
User entered 'No (N)'	System	04 Apr 2021 13:57:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-04T08:57:22-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'aae4f16c-f493-42a7-9620-985138fad846'	System	04 Apr 2021 13:57:24
User entered '04 Apr 2021 08:57:22'	System	04 Apr 2021 13:57:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-11T06:30:39-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0e883222-c0ff-4bf0-a928-2d3c31883e96'	System	11 Apr 2021 11:30:52
User entered 'No (N)'	System	11 Apr 2021 11:30:52

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-11T06:30:46-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0e883222-c0ff-4bf0-a928-2d3c31883e96'	System	11 Apr 2021 11:30:52
User entered 'No (N)'	System	11 Apr 2021 11:30:52

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-11T06:30:49-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '0e883222-c0ff-4bf0-a928-2d3c31883e96'	System	11 Apr 2021 11:30:52
User entered '11 Apr 2021 06:30:49'	System	11 Apr 2021 11:30:52

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-18T04:33:40-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '7ba00638-b6ca-416d-9ae4-d2806d16fa03'	System	18 Apr 2021 09:33:49
User entered 'No (N)'	System	18 Apr 2021 09:33:49

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-18T04:33:44-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '7ba00638-b6ca-416d-9ae4-d2806d16fa03'	System	18 Apr 2021 09:33:49
User entered 'No (N)'	System	18 Apr 2021 09:33:49

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-18T04:33:47-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '7ba00638-b6ca-416d-9ae4-d2806d16fa03'	System	18 Apr 2021 09:33:49
User entered '18 Apr 2021 04:33:47'	System	18 Apr 2021 09:33:49

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-25T06:10:14-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b446b6f1-c1c8-4c4e-9040-b4d8faab32d3'	System	25 Apr 2021 11:10:24
User entered 'No (N)'	System	25 Apr 2021 11:10:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-25T06:10:18-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b446b6f1-c1c8-4c4e-9040-b4d8faab32d3'	System	25 Apr 2021 11:10:24
User entered 'No (N)'	System	25 Apr 2021 11:10:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-04-25T06:10:21-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b446b6f1-c1c8-4c4e-9040-b4d8faab32d3'	System	25 Apr 2021 11:10:24
User entered '25 Apr 2021 06:10:21'	System	25 Apr 2021 11:10:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-05-02T05:49:37-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b5dc50f3-d830-4887-91f0-8142220c9c32'	System	02 May 2021 10:49:54
User entered 'No (N)'	System	02 May 2021 10:49:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Have you been exposed to someone with 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 (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-05-02T05:49:48-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b5dc50f3-d830-4887-91f0-8142220c9c32'	System	02 May 2021 10:49:54
User entered 'No (N)'	System	02 May 2021 10:49:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-05-02T05:49:51-05:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: 'b5dc50f3-d830-4887-91f0-8142220c9c32'	System	02 May 2021 10:49:54
User entered '02 May 2021 05:49:51'	System	02 May 2021 10:49:54

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:42:24

US3312629

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:05:01

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:42:24
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:42:24

US3312629

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:01

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:49:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-27T09:55:47-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4eb58e8e-86bd-4c85-af66-4ffa6bfc1b35'	System	27 Feb 2021 15:55:59
User entered 'No (N)'	System	27 Feb 2021 15:55:59

US3312629

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:05:01

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:49:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D1165CBE-0A79-47B0-9209-1DFB5203C837)', Time: '2021-02-27T09:55:54-06:00', User OID: 'PatientReportedOutcome (US3312629)', ODM File OID: '4eb58e8e-86bd-4c85-af66-4ffa6bfc1b35' User entered '27 Feb 2021 15:55:54'	System	27 Feb 2021 15:55:59
	System	27 Feb 2021 15:55:59

US3312629

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:06:47

US3312629

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '08 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:06:47

US3312629

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:06:47

US3312629

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:06:47

US3312629

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:06:51

US3312629

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:30:48
User entered 'I'	System	09 Dec 2020 18:06:51

US3312629

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 22:20:20

US3312629

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered '11 Jan 2021'	(b) (4), (b) (6)	11 Jan 2021 22:20:20

US3312629

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Jan 2021 22:20:20

US3312629

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Jan 2021 22:20:20

US3312629

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Jan 2021 22:20:23

US3312629

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User entered 'I'	System	11 Jan 2021 22:20:23

US3312629

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 20:51:26

US3312629

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered '10 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 20:51:26

US3312629

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 20:51:26

US3312629

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 20:51:26

US3312629

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 20:51:39

US3312629

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User entered 'I'	System	16 Feb 2021 20:51:39

US3312629

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 21:49:12

US3312629

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered '09 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 21:49:12

US3312629

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 21:49:12

US3312629

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 21:49:12

US3312629

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 21:49:30

US3312629

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:53:32
User entered 'I'	System	09 Mar 2021 21:49:30

US3312629

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:07

US3312629

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:07

US3312629

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:07

US3312629

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered 'VISIT4'	System	29 Mar 2021 18:41:07

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered empty.	System	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered empty.	System	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered empty.	System	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered empty.	System	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered empty.	System	29 Mar 2021 18:41:20

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44

US3312629

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44

US3312629

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:31

US3312629

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:31

US3312629

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:45

US3312629

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:45

US3312629

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '10:36'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:45

US3312629

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered '29 Mar 2021 10:36'	System	29 Mar 2021 18:41:45

US3312629

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:41:54

US3312629

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:07:44
User entered 'I'	System	29 Mar 2021 18:41:54

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:05:01

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:16:30
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:05:01

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:16:30
User entered '09:53'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:05:01

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:17
User entered '23 Nov 2020 09:53'	System	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:05:01

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:16:30
User entered 'Safety Call (Safety Call)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:05:01

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:17
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:16:30
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:19:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Day 1 (Day 1)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '21 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:05:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:05:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User entered '%'	System	18 Dec 2020 18:05:51
User entered empty.	System	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:05:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:05:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:05:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:21:37

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Day 2 (Day 2)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '22 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:05:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:05:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User entered '%'	System	18 Dec 2020 18:05:51
User entered empty.	System	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Dec 2020 18:05:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:05:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered empty.	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:05:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:08

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Day 3 (Day 3)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '0'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '100'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User entered '%'	System	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '97.8' F	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:05:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:22:46

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User closed query 'Per CDM: Day 4 and Day 7 are recorded with duplicate dates. Please review and update the dates to resolve the duplicate entries and update the rest of the symptom log as necessary so that the days and dates are in the expected order.'	(b) (4), (b) (6)	26 Apr 2021 09:26:08
' (Site from DM). Query 'Per CDM: Day 4 and Day 7 are recorded with duplicate dates. Please review and update the dates to resolve the duplicate entries and update the rest of the symptom log as necessary so that the days and dates are in the expected order.'	Karol Moore (b) (4) (b) (4)	23 Apr 2021 19:52:10
' answered with 'updated day 7 date' (Site from DM). User opened query 'Per CDM: Day 4 and Day 7 are recorded with duplicate dates. Please review and update the dates to resolve the duplicate entries and update the rest of the symptom log as necessary so that the days and dates are in the expected order.'	(b) (4), (b) (6)	23 Apr 2021 07:15:51
' (Site from DM). User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 19:39:04
User entered 'Day 4 (Day 4)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '24 Nov 2020'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '0'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '100'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User entered '%'	System	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '97.5' F	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:05:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:02:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Day 5 (Day 5)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '25 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '99'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User entered '%'	System	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '98' F	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:05:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:13

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Day 6 (Day 6)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '26 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '99'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User entered '%'	System	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '98.4' F	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:05:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 15:59:56

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Day 7 (Day 7)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	24 Apr 2021 14:42:32
DataPoint Un-verified.	(b) (4)	23 Apr 2021 19:51:20
Signature has been broken.	Karol Moore (b) (4)	23 Apr 2021 19:51:20
User entered '27 Nov 2020' reason for change: Data Entry Error	(b) (4)	23 Apr 2021 19:51:20
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4)	10 Dec 2020 21:17:37
User entered '24 Nov 2020'	(b) (4), (b) (6)	
	Karol Moore (b) (4)	01 Dec 2020 16:00:29
	(b) (4)	

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '0'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '99'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User entered '%'	System	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered '97.9' F	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Mild (Mild)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'Moderate (Moderate)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:05:01

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:21
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:17:37
User entered 'None (None)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:29

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered 'No (N)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 21:19:56
User entered empty.	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:05:01

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:26
User entered '0'	System	01 Dec 2020 16:00:48

US3312629

Folder: Covid-19 Assessment 23 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:05:01

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:31:30
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'No (N)'	(b) (4) Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:00:53

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:05:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:01:51

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:05:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered '25 Nov 2020'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:05:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:01:51

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:05:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered '27 Nov 2020'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:05:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:01:51

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:05:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:05:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:01:51

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:05:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:05:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:01:51

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:05:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:05:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:01:51

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:05:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:05:01

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karol Moore (b) (4) (b) (4)	01 Dec 2020 16:01:51

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:05:01

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:51
	(b) (4)	

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '23 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Clinic (Clinic)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User entered 'SICKD1'	System	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '23 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '11:33'	(b) (4)	23 Nov 2020 20:24:23
	Karol Moore (b) (4)	
	(b) (4)	

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User entered '23 Nov 2020 11:33'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '65' in	(b) (4)	23 Nov 2020 20:24:23
DataPoint set to visible.	Karol Moore (b) (4)	23 Nov 2020 20:23:49
	(b) (4)	
	System	

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '217.8' lb	(b) (4) Karol Moore (b) (4)	23 Nov 2020 20:24:23
DataPoint set to visible.	(b) (4) System	23 Nov 2020 20:23:49

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '97.8' F	(b) (4)	23 Nov 2020 20:24:23
	Karol Moore (b) (4)	
	(b) (4)	

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Oral (Oral)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '80'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User entered 'bpm'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '16'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User entered 'breaths/min'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '114'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User entered 'mmHg'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '82'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User entered 'mmHg'	System	23 Nov 2020 20:24:23

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36

US3312629

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36

US3312629

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:32

US3312629

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '23 Nov 2020'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:32

US3312629

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:05:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:41

US3312629

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:52:36
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 11:47:05
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'CONFIRMED SHIPPED, ACCESSION NUMBER 1F60IAP' (Site from DM).	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 17:33:23
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 23 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 06:04:09
User entered '23 Nov 2020'	Karol Moore (b) (4) (b) (4)	23 Nov 2020 20:24:41

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 16:01:07
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:07
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:07
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	01 Dec 2020 16:01:07

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:01:11

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:01:11

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:01:11

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:01:11

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:11
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 16:01:11

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 16:01:14
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:14
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:05:01

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	01 Dec 2020 16:01:18
	(b) (4)	

US3312629

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:05:01

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	01 Dec 2020 16:01:18
	(b) (4)	

US3312629

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:32:41

US3312629

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:32:41

US3312629

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:32:53
User entered 'Home (Home)'	(b) (4), (b) (6)	05 Feb 2021 19:32:41

US3312629

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

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 19:32:41

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:01:04

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:01:04

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '1'	System	05 Feb 2021 19:33:26

US3312629

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

Form: Unblinding

Generated On: 09 Jun 2021 17:05:01

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'I'	System	05 Feb 2021 19:33:26

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered empty.	System	05 Feb 2021 19:35:20
DataPoint set to visible.	System	05 Feb 2021 19:33:26

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered empty.	System	05 Feb 2021 19:35:20
DataPoint set to visible.	System	05 Feb 2021 19:33:26

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '10:28'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '22 Jan 2021 10:28'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '68'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'bpm'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '14'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'breaths/min'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '120'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '68'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:05:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered empty.	System	05 Feb 2021 19:35:20
DataPoint set to visible.	System	05 Feb 2021 19:33:26

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '11:58'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '22 Jan 2021 11:58'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '67'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'bpm'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'breaths/min'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '110'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '70'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:20

US3312629

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	05 Feb 2021 19:35:20

US3312629

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:29

US3312629

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:29

US3312629

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

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:44

US3312629

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

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mRNA-1273'	System	05 Feb 2021 19:35:44
DataPoint set to visible.	System	05 Feb 2021 19:33:26

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '11:27'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '22 Jan 2021 11:27'	System	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'ONCE'	System	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 19:35:44

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:37

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:37

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '10:03'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:37

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:05:01

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '22 Jan 2021 10:03'	System	05 Feb 2021 19:33:37

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:48

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:01

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:48

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:01

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '10:02'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:48

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:05:01

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '22 Jan 2021 10:02'	System	05 Feb 2021 19:33:48

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:33:57

US3312629

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'I'	System	05 Feb 2021 19:33:57

US3312629

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:44:15

US3312629

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:44:15

US3312629

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:44:15

US3312629

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:44:15

US3312629

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:44:20

US3312629

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'I'	System	05 Feb 2021 19:44:20

US3312629

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '1'	System	05 Feb 2021 19:44:20
DataPoint set to visible.	System	05 Feb 2021 19:44:20

US3312629

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:14:33

US3312629

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:14:33

US3312629

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:14:33

US3312629

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:05:01

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'OLD29'	System	01 Mar 2021 15:14:33

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '11:30'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '26 Feb 2021 11:30'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '91'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'bpm'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '14'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'breaths/min'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '114'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '64'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:05:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '12:48'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '26 Feb 2021 12:48'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '93'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'bpm'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '16'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'breaths/min'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '117'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '62'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:05:01

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mmHg'	System	01 Mar 2021 15:16:17

US3312629

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:26

US3312629

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:05:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:26

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'mRNA-1273'	System	01 Mar 2021 15:16:41
DataPoint set to visible.	System	05 Feb 2021 19:44:20

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered '12:17'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered '26 Feb 2021 12:17'	System	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'ONCE'	System	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:05:01

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 15:16:41

US3312629

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:16:47

US3312629

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'I'	System	01 Mar 2021 15:16:47

US3312629

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:49:56

US3312629

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered '08 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:49:56

US3312629

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:49:56

US3312629

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:05:01

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:49:56

US3312629

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:50:01

US3312629

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:05:01

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:14:44
User entered 'I'	System	16 Mar 2021 17:50:01

US3312629

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:05:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:23:06
User signature succeeded.	Carlos Fierro (b) (4)	12 Mar 2021 16:10:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:46:09

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:11:33
User entered 'USA-US300-2020-mRNA-1273-P301000012'	System	10 Nov 2020 22:11:29
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 22:11:29

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 18:54:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 18:54:35
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 18:53:40
User entered 'small bowel obstruction'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4)	23 Nov 2020 18:53:28
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'Grade 3 correct as entered. Per source, Grade 4 is not an option.' (Site from Safety).	(b) (4), (b) (6)	
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'Grade 3 correct as entered. Per source, Grade 4 is not an option.' (Site from Safety).	Karol Moore (b) (4)	20 Nov 2020 16:01:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	19 Nov 2020 13:50:22
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:54:13
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject still currently admitted' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 18:53:24
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Nov 2020 18:53:00
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:53:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:53:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Adverse Event form regarding "Mild hypokalemia". Please consider adding this under Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:30:20
User closed query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Concomitant Procedure form regarding IV fluids. Please consider adding this under Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 14:30:14
Query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Concomitant Procedure form regarding IV fluids. Please consider adding this under Concomitant Procedure form. Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:44:26
Query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Adverse Event form regarding "Mild hypokalemia". Please consider adding this under Concomitant Procedure form. Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:44:22
User opened query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Adverse Event form regarding "Mild hypokalemia". Please consider adding this under Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:56:33
User closed query 'Per DM CLR: SAE Narrative = MILD HYPOKALEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:56:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per CDM CLR re-query: Thank you for your answer. However, there are still no updates made on Concomitant Procedure form regarding IV fluids. Please consider adding this under Concomitant Procedure form. Thank you!' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:44:53
User closed query 'Per DM CLR: SAE Narrative = IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:44:53
Query 'Per DM CLR: SAE Narrative = MILD HYPOKALEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:22:27
Query 'Per DM CLR: SAE Narrative = IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:22:23
User closed query 'Per DM CLR: Narrative indicates that subject had "CT SCAN & XRAYs". However, these diagnostic procedures are not recorded in their respective eCRF. Review and record these as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 08:43:03
Query 'Per DM CLR: Narrative indicates that subject had "CT SCAN & XRAYs". However, these diagnostic procedures are not recorded in their respective eCRF. Review and record these as appropriate. Otherwise, clarify. ' answered with 'diagnostic tests not procedures-NA on Con PROCEDURE page' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 00:54:30
User opened query 'Per DM CLR: SAE Narrative = MILD HYPOKALEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 23:46:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = IV FLUIDS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 23:46:01

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
Query 'PER PHONE CALL WITH SUBJECT 11/09/2020 53 Y/O WOMAN WITH H/O DIVERTICULOSIS AND PARTIAL COLECTOMY, SLEEVE GASTRECTOMY, INCISIONAL HERNIAS, & HIATAL HERNIA WHO DEVELOPED ABDOMINAL PAIN ON 06NOV2020 THAT RESULTED IN ER VISIT. SMALL BOWEL OBSTRUCTION WAS DIAGNOSED; EVAL INCLUDED CT SCAN AND XRAYS.TREATED WITH IV FENTANYL AND TORADOL AND NPO WITHOUT NG TUBE,HER DIET WAS ADVANCED TO CLEAR LIQUIDS BY 08NOV2020. HER CARE TEAM HOPES TO ADVANCE TO FULL LIQUIDS TODAY, 09NOV2020. SUBJECTâ€™S PAIN WAS WELL CONTROLLED AND SHE WAS IN NO DISTRESS AT TIME OF PHONE CONTACT TODAY. SBO BELIEVED TO BE RELATED TO ADHESIONS RELATED TO PREVIOUS PROCEDURES. THIS IS AN SAE OF SBO, NR TO IP. UPDATE 11NOV2020: SUBJECT DISCHARGED FROM HOSPITAL WITHOUT ADDITIONAL INTERVENTION, HAS HAD BOWEL MOVEMENTS AND WITHOUT PAIN. MR PENDING.UPDATE:MEDICAL RECORDS REVIEWED.SUBJECT WAS ADMITTED 06NOV2020 WITH PARTIAL SMALL BOWEL OBSTRUCTION RELATED TO ADHESIONS FROM HISTORY OF MULTIPLE ABDOMINAL SURGERIES.ON DATE OF ADMISSION DEVELOPED EPIGASTRIC ABDOMINAL PAIN AT APPROXIMATELY 12:45 PM THAT PROGRESSIVELY WORSENERD TO 8 OUT OF 10 SEVERITY OVER HOURS.SELF INDUCED EMESIS (NON-BLOODY) DID NOT RELIEVE PAIN.SHE WENT TO LOCAL ER WHERE CARE WAS INITIATED BUT TRANSFERRED TO ANOTHER SAME DAY.OVERALL WORK-UP REVEALED NEGATIVE COVID TEST 06NOV2020,DILATED LOOPS OF BOWEL WITHOUT EVIDENCE OF PNEUMATOSIS OR	(b) (4), (b) (6)	29 Jan 2021 23:45:54

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
ISCHEMIA AND CONSISTENT WITH PARTIAL SMALL BOWEL OBSTRUCTION ON IMAGING, NEUTROPHIL ELEVATION TO 9000/MICROL WITHOUT SIGNS OF INFECTION CONSISTENT WITH STRESS AND PAIN RELATED ELEVATION, ABDOMINAL PAIN THAT RESOLVED WITH IV PAIN MEDS, AND LACTATE LEVEL OF 3.14 THAT DECREASED TO 1.3 WITH IV FLUIDS.TREATMENT WAS CONSERVATIVE WITH NPO, THEN ADVANCEMENT OF DIET.ON DAY OF DC 10NOV2020 SUBJECT LOOKED AND FELT WELL, HAD 2 NO' canceled (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PER PHONE CALL WITH SUBJECT 11/09/2020 53 Y/O WOMAN WITH H/O DIVERTICULOSIS AND PARTIAL COLECTOMY, SLEEVE GASTRECTOMY, INCISIONAL HERNIAS, & HIATAL HERNIA WHO DEVELOPED ABDOMINAL PAIN ON 06NOV2020 THAT RESULTED IN ER VISIT. SMALL BOWEL OBSTRUCTION WAS DIAGNOSED; EVAL INCLUDED CT SCAN AND XRAYS.TREATED WITH IV FENTANYL AND TORADOL AND NPO WITHOUT NG TUBE,HER DIET WAS ADVANCED TO CLEAR LIQUIDS BY 08NOV2020. HER CARE TEAM HOPES TO ADVANCE TO FULL LIQUIDS TODAY, 09NOV2020. SUBJECTâ€™S PAIN WAS WELL CONTROLLED AND SHE WAS IN NO DISTRESS AT TIME OF PHONE CONTACT TODAY. SBO BELIEVED TO BE RELATED TO ADHESIONS RELATED TO PREVIOUS PROCEDURES. THIS IS AN SAE OF SBO, NR TO IP. UPDATE 11NOV2020: SUBJECT DISCHARGED FROM HOSPITAL WITHOUT ADDITIONAL INTERVENTION, HAS HAD BOWEL MOVEMENTS AND WITHOUT PAIN. MR PENDING.UPDATE:MEDICAL RECORDS REVIEWED.SUBJECT WAS ADMITTED 06NOV2020 WITH PARTIAL SMALL BOWEL OBSTRUCTION RELATED TO ADHESIONS FROM HISTORY OF MULTIPLE ABDOMINAL SURGERIES.ON DATE OF ADMISSION DEVELOPED EPIGASTRIC ABDOMINAL PAIN AT APPROXIMATELY 12:45 PM THAT PROGRESSIVELY WORSENERD TO 8 OUT OF 10 SEVERITY OVER HOURS.SELF INDUCED EMESIS (NON-BLOODY) DID NOT RELIEVE PAIN.SHE WENT TO LOCAL ER WHERE CARE WAS INITIATED BUT TRANSFERRED TO ANOTHER SAME DAY.OVERALL WORK-UP REVEALED NEGATIVE COVID TEST 06NOV2020,DILATED LOOPS OF BOWEL WITHOUT EVIDENCE OF PNEUMATOSIS OR	(b) (4), (b) (6)	29 Jan 2021 23:45:46

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
ISCHEMIA AND CONSISTENT WITH PARTIAL SMALL BOWEL OBSTRUCTION ON IMAGING, NEUTROPHIL ELEVATION TO 9000/MICROL WITHOUT SIGNS OF INFECTION CONSISTENT WITH STRESS AND PAIN RELATED ELEVATION, ABDOMINAL PAIN THAT RESOLVED WITH IV PAIN MEDS, AND LACTATE LEVEL OF 3.14 THAT DECREASED TO 1.3 WITH IV FLUIDS.TREATMENT WAS CONSERVATIVE WITH NPO, THEN ADVANCEMENT OF DIET.ON DAY OF DC 10NOV2020 SUBJECT LOOKED AND FELT WELL, HAD 2 NO' (Site from DM).		
User opened query 'Per DM CLR: Narrative indicates that subject had "CT SCAN & XRAYs". However, these diagnostic procedures are not recorded in their respective eCRF. Review and record these as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 12:22:33
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:49:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:49:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:49:05
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:48:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PER PHONE CALL with subject 11/09/2020 53 Y/O WOMAN WITH H/O DIVERTICULOSIS AND PARTIAL COLECTOMY, SLEEVE GASTRECTOMY, INCISIONAL HERNIAS, & HIATAL HERNIA WHO DEVELOPED ABDOMINAL PAIN ON 06NOV2020 THAT RESULTED IN ER VISIT. SMALL BOWEL OBSTRUCTION WAS DIAGNOSED; EVAL INCLUDED CT SCAN AND XRAYS.TREATED WITH IV FENTANYL AND TORADOL AND NPO WITHOUT NG Tube,HER DIET WAS ADVANCED TO CLEAR LIQUIDS BY 08NOV2020. HER CARE TEAM HOPES TO ADVANCE TO FULL LIQUIDS TODAY, 09NOV2020. SUBJECT'S PAIN WAS WELL CONTROLLED AND SHE WAS IN NO DISTRESS AT TIME OF PHONE CONTACT TODAY. SBO BELIEVED TO BE RELATED TO ADHESIONS RELATED TO PREVIOUS PROCEDURES. THIS IS AN SAE OF SBO, NR TO IP. UPDATE 11NOV2020: SUBJECT DISCHARGED FROM HOSPITAL WITHOUT ADDITIONAL INTERVENTION, HAS HAD BOWEL MOVEMENTS AND WITHOUT PAIN. MR PENDING.Update:Medical records reviewed.Subject was admitted 06Nov2020 with partial small bowel obstruction related to adhesions from history of multiple abdominal surgeries.On date of admission developed epigastric abdominal pain at approximately 12:45 pm that progressively worsened to 8 out of 10 severity over hours.Self induced emesis (non-bloody) did not relieve pain.She went to local ER where care was initiated but transferred to another same day.Overall work-up revealed negative Covid test 06Nov2020,dilated loops of bowel without evidence of pneumatosis or ischemia and consistent with partial small bowel obstruction on imaging, neutrophil elevation to 9000/microL without signs of infection consistent with stress and pain related elevation, abdominal pain that resolved with iv pain meds, and lactate level of 3.14 that decreased to 1.3	(b) (4), (b) (6)	18 Nov 2020 23:39:17

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[Narrative](#)

Audit	User	Time (GMT)
with iv fluids.Treatment was conservative with npo, then advancement of diet.On day of DC 10Nov2020 subject looked and felt well, had 2 normal bowel movements, and a mild hypokalemia of 3.3 that was corrected.AE resolved' reason for change: Data Entry Error		
User entered 'SUBJECT IS HISTORIAN PER PHONE CALL 11/09/2020 53 Y/O WOMAN WITH H/O DIVERTICULOSIS AND PARTIAL COLECTOMY, SLEEVE GASTRECTOMY, INCISIONAL HERNIAS, AND HIATAL HERNIA WHO DEVELOPED ABDOMINAL PAIN ON 06NOV2020 THAT RESULTED IN ER VISIT. SMALL BOWEL OBSTRUCTION (SBO) WAS DIAGNOSED; EVAL INCLUDED CT SCAN AND XRAYs. SUBJECT WAS TREATED WITH IV FENTANYL AND TORADOL AND NPO WITHOUT NASOGASTRIC TUBE. HER DIET WAS ADVANCED TO CLEAR LIQUIDS BY 08NOV2020. HER CARE TEAM HOPES TO ADVANCE TO FULL LIQUIDS TODAY, 09NOV2020. SUBJECT'S PAIN WAS WELL CONTROLLED AND SHE WAS IN NO DISTRESS AT TIME OF PHONE CONTACT TODAY. SBO BELIEVED TO BE RELATED TO ADHESIONS RELATED TO PREVIOUS PROCEDURES. THIS IS AN SAE OF SBO, NR TO IP. update 11Nov2020: subject discharged from hospital without additional intervention, has had bowel movements and without pain. medical records pending' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:54:42

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is historian per phone call 11/09/2020 53 y/o woman with h/o diverticulosis and partial colectomy, sleeve gastrectomy, incisional hernias, and hiatal hernia who developed abdominal pain on 06Nov2020 that resulted in ER visit. Small bowel obstruction (SBO) was diagnosed; eval included CT scan and Xrays. Subject was treated with iv fentanyl and toradol and NPO without nasogastric tube. Her diet was advanced to clear liquids by 08Nov2020. Her care team hopes to advance to full liquids today, 09Nov2020. Subject's pain was well controlled and she was in no distress at time of phone contact today. SBO believed to be related to adhesions related to previous procedures. This is an SAE of SBO, NR to IP.'	(b) (4), (b) (6)	09 Nov 2020 18:53:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Nov 2020 18:53:00

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Epicondylitis, LLT: Tennis elbow - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 00:10:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 00:10:50
Data point term sent to Coder	System	19 Nov 2020 20:58:21
User entered 'LEFT TENNIS ELBOW (lateral epicondylitis)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User entered empty.	System	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User entered empty.	System	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per CDM: Per CCG pg.33,Action taken with investigational product is expected to be 'Not applicable' If adverse event started AFTER last dose.Please consider to update this field appropriately or else, clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 10:52:42
Query 'Per CDM: Per CCG pg.33,Action taken with investigational product is expected to be 'Not applicable' If adverse event started AFTER last dose.Please consider to update this field appropriately or else, clarify. Thank you.' answered with 'updated' (Site from DM).	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:01:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	25 Nov 2020 17:00:49
User opened query 'Per CDM: Per CCG pg.33,Action taken with investigational product is expected to be 'Not applicable' If adverse event started AFTER last dose.Please consider to update this field appropriately or else, clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 09:40:13
User entered 'None (NONE)'	(b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User entered '0'	System	19 Nov 2020 20:57:30

US3312629

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39
User entered '1'	System	19 Nov 2020 20:57:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral upper respiratory tract infection, LLT: Viral upper respiratory tract infection - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 13:26:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 13:26:56
Data point term sent to Coder	System	17 Mar 2021 19:20:29
Coding entries removed.	(b) (4), (b) (6)	17 Mar 2021 19:20:00
User entered 'UPPER RESPIRATORY INFECTION (Enterovirus/rhinovirus)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Mar 2021 19:20:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:47:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Feb 2021 15:47:58
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:24:55
Data point term sent to Coder	System	11 Feb 2021 18:23:39
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 18:23:25
Coding entries removed.	(b) (4), (b) (6)	11 Feb 2021 18:23:17
User entered 'UPPER RESPIRATORY INFECTION (Unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 18:23:17
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 08:31:44

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 18:29:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 18:29:00
Data point term sent to Coder	System	09 Dec 2020 18:28:24
User entered 'Upper respiratory infection'	(b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User entered empty.	System	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
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)	09 Dec 2020 18:28:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	09 Dec 2020 18:28:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Dec 2020 18:28:00
User entered '30 Nov 2020'	(b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User entered empty.	System	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:30:41
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 19:44:42
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 23:46:46
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 18:28:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User entered '0'	System	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44
User entered 'I'	System	09 Dec 2020 18:28:00

US3312629

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:44

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Gastroenteritis, LLT: Gastroenteritis - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 18:35:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 18:35:07
Data point term sent to Coder	System	09 Dec 2020 18:33:29
User entered 'gastroenteritis'	(b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User entered empty.	System	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User entered empty.	System	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User entered '0'	System	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49
User entered 'I'	System	09 Dec 2020 18:33:15

US3312629

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:49

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:39:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:39:23
Data point term sent to Coder	System	16 Feb 2021 21:38:59
User entered 'Hypokalemia'	(b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User entered empty.	System	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User entered empty.	System	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User entered '0'	System	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53
User entered 'I'	System	16 Feb 2021 21:38:39

US3312629

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:53

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Normocytic anaemia, LLT: Normocytic anemia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:44:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Feb 2021 21:44:09
Data point term sent to Coder	System	16 Feb 2021 21:43:04
User entered 'normocytic anemia'	(b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '09 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User entered empty.	System	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:43:17
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User entered empty.	System	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 18:43:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User entered '0'	System	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58
User entered 'I'	System	16 Feb 2021 21:42:05

US3312629

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:05:01

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:20:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:05:01

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:23:06
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:07:27

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 17:10:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:10:26
Data point term sent to Coder	System	05 Oct 2020 17:09:16
User entered 'atorvastatin'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'hypercholesterolemia'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '80'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2010'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:08:53
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:08:53

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 17:10:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:10:26
Data point term sent to Coder	System	05 Oct 2020 17:09:16
User entered 'escitalopram'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'anxiety'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '20'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2018'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:09:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:09:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Oct 2020 04:58:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 04:58:22
Data point term sent to Coder	System	05 Oct 2020 17:10:18
User entered 'pantoprazole'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'current hiatal hernia'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '40'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'twice daily (BID)'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2016'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:10:03
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:10:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 17:13:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:13:28
Data point term sent to Coder	System	05 Oct 2020 17:11:22
User entered 'montelukast'	Karol Moore (b) (4)	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'seasonal allergies'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '10'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'other (OTHER)'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'nightly'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2018'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:10:44
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:10:44

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 12:44:14
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 12:44:14
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 17:12:23
User entered 'amitriptyline'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'migraines'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '50'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'other (OTHER)'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'nightly'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un Feb 2020'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:11:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:11:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 17:15:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:15:20
Data point term sent to Coder	System	05 Oct 2020 17:14:27
User entered 'famotidine'	Karol Moore (b) (4)	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'acid reflux'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '20'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'twice daily (BID)'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2016'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:13:39
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:13:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 17:15:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:15:20
Data point term sent to Coder	System	05 Oct 2020 17:14:27
User entered 'loratidine'	Karol Moore (b) (4)	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'seasonal allergies'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '10'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2018'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:14:05
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:14:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 17:16:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:16:23
Data point term sent to Coder	System	05 Oct 2020 17:15:31
User entered 'fluticasone'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'seasonal allergies'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 27.5 MCG, 50 MCG, etc) instead of sprays count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:48:46
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 27.5 MCG, 50 MCG, etc) instead of sprays count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 17:13:25
User entered '50' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 17:13:13
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 27.5 MCG, 50 MCG, etc) instead of sprays count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:14:16
User entered '1'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 17:13:13
	(b) (4)	
User entered 'Other (OTHER)'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Monica Atwood (b) (4)	22 Dec 2020 17:13:13
	(b) (4)	
User entered 'spray'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:35:15
User entered 'twice daily (BID)'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Nasal (NASAL)'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2018'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:14:32
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:35:15
User entered '2'	System	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:14:32

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 17:09:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 17:09:49
Data point term sent to Coder	System	22 Dec 2020 17:09:01
Coding entries removed.	Monica Atwood (b) (4)	22 Dec 2020 17:08:51
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:16:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:16:24
Data point term sent to Coder	System	05 Oct 2020 17:15:31
User entered 'aspirin'	Karol Moore (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:58:10
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 17:09:05
User entered 'CARDIAC PROPHYLAXIS' reason for change: Data Entry Error	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 17:08:51
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:14:39
User entered 'general health maintenance'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '81'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2010'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:15:08
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 17:15:08

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:17:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:17:27
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 17:16:33
User entered 'sumatriptan'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'migraines'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '100'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un Feb 2020'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:16:01
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:01

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 17:17:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:17:28
Data point term sent to Coder	System	05 Oct 2020 17:16:33
User entered 'ibuprofen'	Karol Moore (b) (4) (b) (4)	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'migraines'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '800'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2000'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:16:26
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:26

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:18:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 17:18:32
	(b) (4)	
Data point term sent to Coder	System	05 Oct 2020 17:17:34
User entered 'acetaminophen'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'migraines'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '1000'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mg (mg)'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'as needed (PRN)'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Oral (ORAL)'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'un UNK 2000'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	05 Oct 2020 17:16:47
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 17:16:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: OTHER ANTI OBESITY DRUGS, PRODUCT: LIRAGLUTIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 19:46:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 19:46:34
Data point term sent to Coder	System	06 Oct 2020 19:45:05
User entered 'liraglutide'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'obesity'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '3'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'mL (mL)'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'once daily (QD)'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '01 Jun 2020'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH condition has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:59:45
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH condition has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'UPDATED MEDICAL HISTORY OF OBESITY TO ONGOING' (Site from DM).	Monica Atwood (b) (4) (b) (4)	22 Dec 2020 17:16:57
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding MH condition has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:15:19
User entered 'Yes (Y)'	Karol Moore (b) (4) (b) (4)	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'No (N)'	Karol Moore (b) (4)	06 Oct 2020 19:44:15
	(b) (4)	

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 19:44:15

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 04:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 04:15:42
Data point term sent to Coder	System	09 Nov 2020 18:54:43
User entered 'toradol'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'small bowel obstruction'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '60' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:55:33
User entered '50'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:55:33
User entered 'ug (ug)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:58:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:58:03
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User entered empty.	System	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User entered empty.	System	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:35
User entered empty.	System	09 Nov 2020 18:54:28

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:56:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 03:56:43
Data point term sent to Coder	System	09 Nov 2020 18:55:44
User entered 'fentanyl'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Nov 2020 18:55:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Nov 2020 18:55:10
User entered 'small bowel obstruction' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 18:55:10
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 18:54:58
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '50'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:57:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '08 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	11 Nov 2020 18:57:50
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User entered empty.	System	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User entered empty.	System	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:39
User entered empty.	System	09 Nov 2020 18:54:58

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:30:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 03:30:53
Data point term sent to Coder	System	19 Nov 2020 20:53:16
User entered 'SEASONAL INFLUENZA VACCINE'	(b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'SEASONAL INFLUNEZA PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0.5'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '08 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '08 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User entered empty.	System	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User entered empty.	System	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:42
User entered empty.	System	19 Nov 2020 20:52:29

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
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: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:42:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:42:05
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:15:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 10:15:10
Data point term sent to Coder	System	19 Nov 2020 20:55:18
User entered 'CORTISONE'	(b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'LEFT TENNIS ELBOW'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'INJECTION'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'intraarticular'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '05 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User entered empty.	System	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User entered empty.	System	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:44
User entered empty.	System	19 Nov 2020 20:54:47

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:53:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:53:19
Data point term sent to Coder	System	19 Nov 2020 20:56:19
User entered 'IBUPROFEN'	(b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'LEFT TENNIS ELBOW'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '800'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User entered empty.	System	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User entered empty.	System	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:47
User entered empty.	System	19 Nov 2020 20:56:05

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE/MIGRAINE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:22:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 19:02:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 19:02:47
Data point term sent to Coder	System	12 Mar 2021 19:01:37
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE/MIGRAINE should be recorded, and update con med indication or provide clarification. ' answered with 'UPDATED.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 19:00:49
Coding entries removed.	(b) (4), (b) (6)	12 Mar 2021 19:00:40
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HEADACHE/MIGRAINE should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 02:29:38

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 18:12:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 18:12:08
Data point term sent to Coder	System	09 Dec 2020 18:10:47
User entered 'Acetaminophen'	(b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'UPPER RESPIRATORY INFECTION'	(b) (4)	12 Mar 2021 19:00:40
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Headache'	(b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '1000'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User entered empty.	System	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User entered empty.	System	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:51
User entered empty.	System	09 Dec 2020 18:10:18

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:43:59
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:43:59
Data point term sent to Coder	System	12 Mar 2021 19:01:37
Coding entries removed.	(b) (4), (b) (6)	12 Mar 2021 19:01:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: OTHER COLD PREPARATIONS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL, PRODUCTSYNONYM: NYQUIL COLD & FLU - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 16:10:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 16:10:58
Data point term sent to Coder	System	09 Dec 2020 18:25:20
User entered 'Nyquil (Acetaminophen 650 mg - Dextromethorphan HBr 30 mg - Doxylamine succinate 12.5 mg'	(b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per DM CLR: Please review if indication refers to AE#3 or AE#5. Please reconcile entries so there is an appropriate match.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:23:46
' (Site from DM).		
Query 'Per DM CLR: Please review if indication refers to AE#3 or AE#5. Please reconcile entries so there is an appropriate match.	(b) (4), (b) (6)	12 Mar 2021 19:01:26
' answered with 'UPDATED.' (Site from DM).		
User entered 'UPPER RESPIRATORY INFECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 19:01:21
User opened query 'Per DM CLR: Please review if indication refers to AE#3 or AE#5. Please reconcile entries so there is an appropriate match.	(b) (4), (b) (6)	21 Jan 2021 02:31:10
' (Site from DM).		
User entered 'congestion/runny nose'	(b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '30'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '22 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User entered empty.	System	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User entered empty.	System	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:45:54
User entered empty.	System	09 Dec 2020 18:25:13

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Feb 2021 12:01:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Feb 2021 12:01:51
Data point term sent to Coder	System	06 Feb 2021 18:01:51
Data point term sent to Coder	System	05 Feb 2021 19:42:17
Data point term sent to Coder	System	05 Feb 2021 19:40:14
User entered 'docusate'	(b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Atwood (b) (4)	06 Feb 2021 18:01:13
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'SMALL BOWEL OBSTRUCTION PROPHYLAXIS' reason for change: Data Entry Error	Monica Atwood (b) (4)	06 Feb 2021 18:01:13
	(b) (4)	
User entered 'SMALL BOWEL obstruction, HEALTH MAINTENANCE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 19:42:12
User entered 'small bowelhealth maintenance'	(b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '50'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'every other day (QOD)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '11 Nov 2020'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 19:40:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		05 Feb 2021 19:40:01
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		05 Feb 2021 19:39:51
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 19:39:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 21:09:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 21:09:06
Data point term sent to Coder	System	16 Feb 2021 21:08:31
User entered 'Calcium'	(b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:24:01
Query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:25:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:25:21
User opened query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 18:23:52
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'General health maintenance'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '600'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 21:07:39

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 21:14:01
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Feb 2021 21:14:01
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 21:12:40
User entered 'Vitamin B'	(b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:24:08
Query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:25:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:25:46
User opened query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 18:15:22
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'general health'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 21:12:30

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Feb 2021 21:20:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 21:20:02
Data point term sent to Coder	System	16 Feb 2021 21:18:45
User entered 'multivitamin'	(b) (4), (b) (6) (b) (4)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:24:14
Query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:25:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:25:55
User opened query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 18:24:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'general health'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '1'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'un UNK 1990'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 21:17:51

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 21:20:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 21:20:03
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 21:18:45
User entered 'fish oil'	(b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:24:20
Query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:26:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	12 Mar 2021 17:26:05
User opened query 'Per CDM: According to CCGs: "Prophylaxis applies to any medications used for prevention (i.e. vitamins, supplements, ASA (cardiac), bone maintenance, etc.)". Kindly review if this field should be updated, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 18:24:42
User entered 'No (N)'	(b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'general health'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '2000'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 21:18:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: GLUCOSE;SODIUM CHLORIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:54:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:54:32
User signature succeeded.	Carlos Fierro (b) (4) (b) (4)	07 Apr 2021 19:38:27
User closed query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:10:19
Data point term sent to Coder	System	19 Mar 2021 14:27:11
Query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Karol Moore (b) (4) (b) (4)	19 Mar 2021 14:26:47
Coding entries removed.	Karol Moore (b) (4) (b) (4)	19 Mar 2021 14:26:34
User entered 'INTRAVENOUS FLUIDS (DEXTROSE/SODIUM CHLORIDE SOLUTION)' reason for change: Data Entry Error	Karol Moore (b) (4) (b) (4)	19 Mar 2021 14:26:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:08:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:08:47
Data point term sent to Coder	System	12 Mar 2021 17:26:43

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: The medication cannot be verified as entered. Please update Medication Name to reflect the complete name (trade or generic) of the medication as appropriate. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:48:34
Data point term sent to Coder	System	16 Feb 2021 21:24:49
User entered 'intravenous fluids'	(b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'SMALL BOWEL OBSTRUCTION'	(b) (4)	12 Mar 2021 17:26:40
reason for change: Data Entry Error	(b) (4)	
User entered 'small bower obstruction'	(b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '1000'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User entered empty.	System	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User entered empty.	System	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:00
User entered empty.	System	16 Feb 2021 21:24:03

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 21:34:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 21:34:03
Data point term sent to Coder	System	16 Feb 2021 21:32:55
User entered 'Potassium'	(b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'hypokalemia'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '20'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'meq'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User entered empty.	System	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User entered empty.	System	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:05:01

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:46:03
User entered empty.	System	16 Feb 2021 21:32:04

US3312629

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:05:01

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:38:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:39:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Jan 2021 16:22:40

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered '10/Nov/2020 22:11'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:05:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:05:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered '12/Nov/2020 13:36'	System	12 Nov 2020 18:36:52

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:05:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 18:36:52

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'USA-US300-2020-MRNA-1273-P301000012'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Yes (Y)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'No (N)'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Carlos'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Fierro'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '16300 College Blvd'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'Shawnee'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered 'KS'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 22:11:52
User entered '66219'	System	10 Nov 2020 22:11:29

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 18:58:43
User entered 'US'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:05:01

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Nov 2020 18:58:51
User entered '2'	System	12 Nov 2020 18:36:52
User entered '1'	System	10 Nov 2020 22:11:58

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:05:01

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered '19/Nov/2020 13:58'	System	19 Nov 2020 18:58:51

US3312629

Folder: SAE USA-US300-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:05:01

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Carlos Fierro (b) (4)	07 Apr 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:25:35
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 18:58:51