

US3812229 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:52:44

All time stamps listed in this document are displayed in GMT

US3812229

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 23:28:52

Generated On: 10 Jun 2021 09:52:44

[Participant ID](#)

US3812229

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

US3812229

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	81
Age Units	YEARS
Age (Derived)	81
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 23:29:11

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Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 23:29:11

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 23:29:11

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Feb 2021 23:29:11

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	ARTHRITIS IN LOWER BACK
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 (5)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Start Year (derived)	1973
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	ALCOHOL USE 3-4 WEEK
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	GLAUCOMA
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 (18)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	BENIGN HYPERTENSION WITH CHRONIC KIDNEY DISEASE TYPE 3
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 (19)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	DEGENERATIVE JOINT DISEASE
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	OSTEOARTHRITIS BILATERAL KNEES
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2009
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2009
Stop Year (derived)	2009

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	BILATERAL HEARING AIDS
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 (27)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	BILATERAL HEARING LOSS
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 (28)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	HYPERLIPIDEMIA
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 (29)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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 (30)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	RIGHT LEFT SCIATICA
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (31)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	LEFT KNEE ARTHOSCOPY
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 (32)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	LEFT KNEE ACL TEAR X2
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 (33)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	BARRETS ESOPHAGUS
Start date (dd MMM yyyy)	UN AUG 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)	AUG 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (34)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	OSTEOPENIA
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 (35)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 1945
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1945
Start Year (derived)	1945
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (36)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	BILATERAL BUNIONECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (37)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	BILATERAL BUNIONS
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (38)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Condition	VITAMIN D DEFICIENCY
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: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:13 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:13
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	190.4 lb
BMI (<i>xxx.x</i>)	31.75047 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	96 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812229

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

US3812229

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 1970

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) _____

Date of last menstruation unknown False

US3812229

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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	SOCIAL BEHAVIOR, LARGE GROUP EVENTS

US3812229

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 186981

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 ☒

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Height	65 in
Weight	190.4 lb

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Height	65 in
Weight	190.4 lb
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)	21 AUG 2020
Time of assessment (00:00-23:59)	08:13 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:13
Temperature (xxx.x)	96 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Height	65 in
Weight	190.4 lb
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)	21 AUG 2020
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:11
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3812229

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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.

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 09:38

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

US3812229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	21 AUG 2020 09:20

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:23	21 AUG 2020 09:23
Nasopharyngeal Swab 2	No		

US3812229

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 21 AUG 2020 10:18

PC Open Date & Time 21 AUG 2020 09:58

PC Close Date & Time 21 AUG 2020 12:28

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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 96.5 °F

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

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

PC Time Stamp	21 AUG 2020 13:47
PC Open Date & Time	21 AUG 2020 13:23
PC Close Date & Time	22 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 12:13

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

23 AUG 2020 14:26

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

24 AUG 2020 12:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 19:05

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 14:43

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 15:40

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 10:19

PC Open Date & Time

21 AUG 2020 09:58

PC Close Date & Time

21 AUG 2020 12:28

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

21 AUG 2020 13:51

PC Open Date & Time

21 AUG 2020 13:23

PC Close Date & Time

22 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

22 AUG 2020 12:15

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

23 AUG 2020 14:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

24 AUG 2020 12:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

25 AUG 2020 19:08

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

26 AUG 2020 14:44

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

27 AUG 2020 15:41

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 10:20
PC Open Date & Time	21 AUG 2020 09:58
PC Close Date & Time	21 AUG 2020 12:28

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 13:49
PC Open Date & Time	21 AUG 2020 13:23
PC Close Date & Time	22 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

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 ☒

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:14
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

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 ☒

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 14:30
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

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 ☒

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:03
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

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 ☒

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 19:09
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 14:54
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

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)

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 15:41
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3812229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

SUBJECT IN CONVALESCENT
PERIOD, NO SAFETY CALL
MADE OUTSIDE OF ILLNESS
CONTACT

US3812229

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 23:29:12

Generated On: 10 Jun 2021 09:52:44

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)	18 SEP 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:19
Temperature (xxx.x)	96.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:29:12

Generated On: 10 Jun 2021 09:52:44

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)	18 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 11:25
Temperature (xxx.x)	96.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3812229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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.

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 10:43 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 10:43

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

US3812229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	10:35 (24 HR)
Collection date and time (derived)	18 SEP 2020 10:35

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:40	18 SEP 2020 10:40
Nasopharyngeal Swab 2	No		

US3812229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

96.2 °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 SEP 2020 11:22

PC Open Date & Time

18 SEP 2020 11:03

PC Close Date & Time

18 SEP 2020 13:33

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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 95.4 °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	19 SEP 2020 09:49
PC Open Date & Time	18 SEP 2020 14:28
PC Close Date & Time	19 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 12:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

94.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 09:15

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

97.1 °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

21 SEP 2020 22:11

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

95.3 °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

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

97.8 °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

23 SEP 2020 13:10

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:57

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

18 SEP 2020 11:23

PC Open Date & Time

18 SEP 2020 11:03

PC Close Date & Time

18 SEP 2020 13:33

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 09:50

PC Open Date & Time

18 SEP 2020 14:28

PC Close Date & Time

19 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

19 SEP 2020 12:04

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 09:15

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

21 SEP 2020 22:12

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

22 SEP 2020 12:16

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

23 SEP 2020 13:11

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

24 SEP 2020 18:58

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 11:24
PC Open Date & Time	18 SEP 2020 11:03
PC Close Date & Time	18 SEP 2020 13:33

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 09:51
PC Open Date & Time	18 SEP 2020 14:28
PC Close Date & Time	19 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

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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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:05
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

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 ☒

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 09:16
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

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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US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 22:13
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

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 ☒

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

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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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 13:11
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:29:12

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:29:12

Generated On: 10 Jun 2021 09:52:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 OCT 2020
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 10:47
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:29:12

Generated On: 10 Jun 2021 09:52:44

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.

US3812229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:29:12

Generated On: 10 Jun 2021 09:52:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	10:55 (24 HR)
Collection date and time (derived)	14 OCT 2020 10:55

US3812229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:12

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 22:23:37

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 05:59:59

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 11:44:50

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 NOV 2020 08:17:44
Patient Cloud Open Date & Time	18 NOV 2020 00:01
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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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	22 NOV 2020 11:23:39
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

29 NOV 2020 10:25:54

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 09:41:07

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

13 DEC 2020 10:15:30

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 11:42:47

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 DEC 2020 19:24:59
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 11:55:48

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 JAN 2021 10:14:17
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 10:22:09

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 12:28:46

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 16:43:48

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

07 FEB 2021 11:38:21

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 09:48:22

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 03:06:52

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	28 FEB 2021 15:37:35
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 11:03:13

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

14 MAR 2021 19:51:23

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

21 MAR 2021 11:21:02

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 09:34:30

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

04 APR 2021 11:33:38

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

11 APR 2021 10:39:41

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 08:38:21

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 10:37:10

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 18:35:47

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 264

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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="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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

Date and time of submission	
Patient Cloud Open Date & Time	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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="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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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="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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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="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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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="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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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="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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	13 OCT 2022 23:59
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US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3812229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:52:44

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
Yes	Yes	28 FEB 2021 15:38:13

US3812229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

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

Visit date (dd MMM yyyy)	08 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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US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:40:47

Generated On: 10 Jun 2021 09:52:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 10:00
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 MAR 2021

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

US3812229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 08 MAR 2021

Collection time (00:00-23:59) 10:25 (24 HR)

Collection date and time (derived) 08 MAR 2021 10:25

US3812229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 14 Apr 2021 20:06:08

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 20:06:08

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Date of Contact	10 NOV 2020
Time of Contact	11:09
Date and Time of Contact (derived)	10 NOV 2020 11:09
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input 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>

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	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	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Moderate	<input checked="" 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 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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 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"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	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	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Moderate	<input checked="" 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 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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 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"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	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	10 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	97.7 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Moderate	<input checked="" 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 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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 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"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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"/>

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	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	11 NOV 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	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 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 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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 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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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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Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

	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	12 NOV 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.7 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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 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"/>

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Date of Visit	10 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	10 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

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Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Date of Contact	26 AUG 2020
Time of Contact	12:47
Date and Time of Contact (derived)	26 AUG 2020 12:47
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input 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 26 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 AUG 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.3 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 type="radio"/>
	Moderate <input checked="" 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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EAB) (1725)

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US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 checked="" type="radio"/>
	Mild	<input 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 26 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input 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 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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 AUG 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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 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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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 checked="" type="radio"/>
	Mild	<input 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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input 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 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"/>

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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 type="checkbox"/>
Day 8	<input checked="" 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 26 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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	28 AUG 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	97.6 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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EAB) (1725)

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 checked="" type="radio"/>
	Mild	<input 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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input 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 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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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 type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" 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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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	29 AUG 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	97.1 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input 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 checked="" type="radio"/>
	Mild	<input 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 26 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

Symptom Day

Day 1	<input checked="" 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 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 26 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 AUG 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"/>

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 checked="" type="radio"/>
	Mild	<input 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 26 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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"/>

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 AUG 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 checked="" type="radio"/>
	Mild	<input 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 26 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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 26 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 AUG 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 checked="" type="radio"/>
	Mild	<input 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 26 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input 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 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"/>

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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"/>

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 AUG 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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 checked="" type="radio"/>
	Mild	<input 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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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"/>

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

	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 AUG 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 type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" 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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US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Date of Visit	26 AUG 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	26 AUG 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

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 28 Apr 2021 22:16:58

Generated On: 10 Jun 2021 09:52:44

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 AUG 2020
Day 5	Yes	30 AUG 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)	

US3812229

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 NOV 2020
Day 5	NA (COVID-19 Negative)	
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)	

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	12:58 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:58
Height (<i>xxx.x</i>)	65.0 in
Weight (<i>xxx.x</i>)	190.4 lb
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3812229

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 AUG 2020

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 11:20
Height (xxx.x)	65.0 in
Weight (xxx.x)	190.0 lb
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3812229

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 NOV 2020

US3812229

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3812229

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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 (<i>dd MMM yyyy</i>)	14 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

US3812229

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Height	65 in
Weight	193.6 lb
BMI (xxx.x)	32.28409

US3812229

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Height	65 in
Weight	193.6 lb
BMI (xxx.x)	32.28409
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)	14 JAN 2021
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 09:08
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 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)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3812229

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Height	65 in
Weight	193.6 lb
BMI (xxx.x)	32.28409
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)	14 JAN 2021
Time of assessment (00:00-23:59)	10:24 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 10:24
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3812229

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

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3812229

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

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 09:53 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 09:53

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

US3812229

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	09:45 (24 HR)
Collection date and time (derived)	14 JAN 2021 09:45

US3812229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	09:50
Collection Date and Time (derived)	14 JAN 2021 09:50

US3812229

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

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 23:29:10

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 23:29:10

Generated On: 10 Jun 2021 09:52:44

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 FEB 2021
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 08:45
Temperature (xxx.x)	96.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 23:29:10

Generated On: 10 Jun 2021 09:52:44

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 FEB 2021
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:39
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 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

US3812229

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 23:29:10

Generated On: 10 Jun 2021 09:52:44

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.

US3812229

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

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) 11 FEB 2021

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

Treatment Date and Time (derived) 11 FEB 2021 09:09

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

US3812229

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:28:53

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812229

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 23:29:11

Generated On: 10 Jun 2021 09:52:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812229

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	10:00 (24 HR)
Vital Signs Date and Time (derived)	08 MAR 2021 10:00
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812229

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 MAR 2021

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

US3812229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:54:21

Generated On: 10 Jun 2021 09:52:44

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

Collection date (dd MMM yyyy)	08 MAR 2021
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Collection time (00:00-23:59)	10:25 (24 HR)
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Collection date and time (derived)	08 MAR 2021 10:25
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US3812229

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 23:28:52

Generated On: 10 Jun 2021 09:52:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

AEID

Adverse event

FOREIGN BODY IN LEFT EAR

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

07 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
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)	

US3812229

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

AEID

Adverse event

LIGHTHEADEDNESS

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)

14 JAN 2021

Start time (00:00-23:59)

10:15 (24 HR)

AE start date and time (derived)

14 JAN 2021 10:15

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 JAN 2021

End time (00:00-23:59)

10:20 (24 HR)

AE End Date and Time (derived)

14 JAN 2021 10:20

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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EAB) (1725)

US3812229

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

AEID	USA-US111-2021-MRNA-1273-P30 1000012
Adverse event	MYOCARDIAL INFARCTION
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)	25 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	25 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	25 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	27 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

Number of Days in ICU	2
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

81 Y/O FEMALE PRESENTED AT URGENT CARE ON 25FEB2021 WITH A CC OF "WORSENING INDIGESTION" THAT STARTED ON 24FEB2021. SHE COMPLETED A CARDIAC ECHO ON 01FEB2021. LVEF 60-65%. SUBJECT SENT TO ED AFTER AN ABNORMAL EKG READING OF ACUTE STEMI. PAIN WORSENERED AND RADIATED TO R ARM AND R SHOULDER BLADE. GIVEN 324MG ASA AND 0.09MG NITROGLYCERIN. SECOND EKG REPORTED NORMAL SINUS RHYTHM, OCCASIONAL PVC, AND NEW ST SEGMENT CHANGES. ACUTE INFERIOR INFARCT WAS INTERPRETED. A CXR WAS OBTAINED SHOWED MILD DEPENDENT ATELECTASIS. TROPONIN T-BASELINE VALUE WAS HIGH WITH RESULTS OF 46. TROPONIN 2-HR WAS HIGH WITH RESULTS OF 240. A TROPONIN 6-HR WAS HIGH WITH RESULTS OF 911. LDL WAS 109 AND NON HDL WAS 139. SUBJECT HAD A NEGATIVE COVID-19 PCR. CTA OF CHEST SHOWED NO EVIDENCE OF AORTIC ANEURYSM OR PULMONARY EMBOLI. SUBJECT TAKEN TO

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

CATH LAB FOR
CATHETERIZATION WHERE
POSTEROLATERAL BRANCH OF
THE RIGHT CORONARY
ARTERY WAS NOTED TO BE
OCCLUDED. HEPARIN 4,000
UNITS AND NITROGLYCERIN
INFUSION 20MCG/MIN IV
GIVEN. A 2.0X12MM BALLOON
WAS USED FOR ANGIOPLASTY,
BUT SUBJECT COULD NOT BE
STENTED DUE TO SMALL SIZE
AND DID NOT STAY OPEN
DESPITE SEVERAL
ANGIOPLASTY ATTEMPTS.
SUBJECT TRANSFERRED TO
ICU WITH WORSENING PAIN
UNDER BREASTS AND
METALLIC TASTE IN HER
MOUTH. AN ECHO AND EKG
WAS COMPLETED ON
26FEB2021 AND CONFIRMED
CARDIAC STABILITY. SUBJECT
GIVEN 1 NITROGLYCERIN
TRANSDERMAL PATCH FOR
DISCOMFORT. SUBJECT WAS
DISCHARGED IN STABLE
CONDITION ON 27FEB2021
WITH ORDERS OF ASPIRIN 81
MG DAILY, ATORVASTATIN
80MG DAILY AT HS,
FAMOTIDINE 40MG DAILY,
TICAGRELOR 90MG BID, AND
LIDOCAINE 4% TOPICAL PATCH
FOR BACK PAIN. DISCHARGING

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

PHYSICIAN STOPPED
AMLODIPINE 5 MG DAILY,
ESTRADIOL 1 MG DAILY, AND
ETODOLAC 400MG DAILY
UNTIL HER FOLLOW UP VISIT
ON 03MAR21. SUBJECT SEEN IN
OUR CLINIC FOR OLD57 AND
D209 VISIT. NO CHANGES IN
MEDICATIONS PRESCRIBED AT
DISCHARGE, BUT REPORTS
NEVER UTILIZED LIDOCANE
PATCH, THEREFORE NOT
REFLECTED IN CONMEDS

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)	1

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

AEID	
Adverse event	GRADE 2 SYSTOLIC HEART MURMUR
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)	14 JAN 2021
Start time (00:00-23:59)	09:30 (24 HR)
AE start date and time (derived)	14 JAN 2021 09:30
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input checked="" type="radio"/>
	Recovered/Resolved <input type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

AEID	
Adverse event	COVID LIKE ILLNESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 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)	17 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____ _____

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

AEID	
Adverse event	COVID LIKE ILLNESS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 AUG 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)	29 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 02:45:56

Generated On: 10 Jun 2021 09:52:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
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) 20 Feb 2021 23:28:52

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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) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 175

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) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:35:07

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Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication HORMONE REPLACEMENT
THERAPY DUE TO
POST-MENOPAUSAL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication CLOMAZEPAM

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication ETODOLAC

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS IN LOWER
BACK

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:35:07

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	27 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:35:07

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Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify MIST

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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 2016	
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) _____		
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 (6)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:35:07

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	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	27 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LOW BACK PAIN

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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)		4 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication COVID LIKE ILLNESS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 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 (9)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTATIVE

Dose per administration 1

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

If dose unit is Other, specify DOSE

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) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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)		03 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)		03 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 (10)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication SENOKOT

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 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)		18 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 (11)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication ICAPS

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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)	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 (12)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

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 (12)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication BRILINTA

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 90

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) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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)	28 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

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 (14)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 324

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 0.9

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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		SUBLINGUAL
Start date (dd MMM yyyy)	25 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 4000

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

If dose unit is Other, specify UNITS

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) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 25 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication MYOCARDIAL INFARCTION

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 (19)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	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)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication NITROGLYCERIN PATCH

Prophylaxis Yes ☐
No ☒

Indication CAD

Dose per administration 1

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

If dose unit is Other, specify UNK

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 (20)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

Name of Medication BOTOX

Prophylaxis Yes ☒
No ☐

Indication WRINKLE PREVENTION

Dose per administration 10

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

If dose unit is Other, specify UNITS

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 (21)

Data signed: (b) (4) 28 Apr 2021 13:35:07

Generated On: 10 Jun 2021 09:52:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN UNK 2017		
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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 23:28:52

Generated On: 10 Jun 2021 09:52:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 21:55:48

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
7 SEP 2020	REMOVAL OF FOREIGN BODY	Adverse Event	
25 FEB 2021	BALLOON ANGIOPLASTY	Adverse Event	
25 FEB 2021	EKG	Adverse Event	
25 FEB 2021	REPEAT EKG	Adverse Event	
25 FEB 2021	CHEST XRAY	Adverse Event	
25 FEB 2021	PRE SURGICAL REQUIRED COVID PCR, NEGATIVE.	Adverse Event	
25 FEB 2021	COMPUTERIZED TOMOGRAPHY ANGIOGRAPHY	Adverse Event	
26 FEB 2021	EKG	Adverse Event	
26 FEB 2021	CARDIAC ECHO	Adverse Event	
25 FEB 2021	INFLUENZA A/B	Adverse Event	
25 FEB 2021	RSV	Adverse Event	

US3812229

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:52:44

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

US3812229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:52:44

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 ☐

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/MAR/2021 10:49
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

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/MAR/2021 11:47
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

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/MAR/2021 08:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/MAR/2021 09:16
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

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/MAR/2021 14:49
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

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/APR/2021 11:47
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

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:52:44

SAEID	USA-US111-2021-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 checked="" type="radio"/> No <input 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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/APR/2021 11:58
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

US3812229 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812229

Form: Participant Creation

Generated On: 10 Jun 2021 09:52:44

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 22:25:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
User entered 'US3812229'	RWS_ENDPOINT	21 Aug 2020 13:54:21
	ENDPOINT (b) (4)	

US3812229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:31:58
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:14

US3812229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:31:58
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:54:22

US3812229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:31:58
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:14

US3812229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'SCRN'	System	21 Aug 2020 15:12:14

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered (b) (6) 1939'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:54:23

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:39
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:13:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:13:17
User entered '81' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	21 Aug 2020 15:13:17
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:12:45
User entered empty.	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'YEARS'	System	21 Aug 2020 15:13:17
User entered empty.	System	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '81'	System	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered 'Female (F)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered 'I'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered '0'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered '0'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered '0'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered '0'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered '0'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered empty.	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered '0'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:39
User entered '0'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:45

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:52
User entered '21 Aug 2020'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Aug 2020'	System	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2020'	System	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:52
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:13:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 15:13:02
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	Heather Cherniawski (b) (4)	21 Aug 2020 15:13:02
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 15:12:55
User entered empty.	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:52
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:52
User entered empty.	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:52
User entered empty.	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:32:52
User entered 'No (N)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:12:55

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 13:54:22

US3812229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'I'	System	21 Aug 2020 15:13:27

US3812229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:49
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:13:27

US3812229

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:52:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:34:44

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:57:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 10:57:25
Data point term sent to Coder	System	05 Oct 2020 00:02:28
Coding entries removed.	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:02:11
User entered 'TUBAL LIGATION-BILATERAL' reason for change: Per Query Resolution	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:02:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:37:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:37:37
Data point term sent to Coder	System	06 Sep 2020 19:36:33
User entered 'TUBAL LIGATION'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1970'	Karen Knapp (b) (4)	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1970'	Karen Knapp (b) (4)	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1970'	System	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1970'	System	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1970'	System	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1970'	System	06 Sep 2020 19:35:38

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:37:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:37:37
Data point term sent to Coder	System	06 Sep 2020 19:36:33
User entered 'HYPOTHYROIDISM'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2005'	Karen Knapp (b) (4)	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2005'	System	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2005'	System	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:35:53

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:37:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:37:37
Data point term sent to Coder	System	06 Sep 2020 19:36:33
User entered 'RESTLESS LEG SYNDROME'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2015'	Karen Knapp (b) (4)	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2015'	System	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2015'	System	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:36:13

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Spondyloarthropathies, PT: Spondylitis, LLT: Back arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:19:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:19:40
Data point term sent to Coder	System	06 Sep 2020 19:37:34
User entered 'ARTHRITIS IN LOWER BACK'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2010'	Karen Knapp (b) (4)	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2010'	System	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2010'	System	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:36:46

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:38:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:38:37
Data point term sent to Coder	System	06 Sep 2020 19:37:34
User entered 'HYPERTENSION'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2015'	Karen Knapp (b) (4)	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2015'	System	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2015'	System	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:37:00

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Gallbladder removal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:12:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Sep 2020 19:12:37
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)	06 Sep 2020 19:38:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:38:37
Data point term sent to Coder	System	06 Sep 2020 19:37:34
User entered 'GALLBLADDER REMOVED'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1998'	Karen Knapp (b) (4)	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1998'	Karen Knapp (b) (4)	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1998'	System	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1998'	System	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1998'	System	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1998'	System	06 Sep 2020 19:37:26

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Inflammation gallbladder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:39:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:39:37
Data point term sent to Coder	System	06 Sep 2020 19:38:34
User entered 'GALLBLADDER INFLAMED'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1998'	Karen Knapp (b) (4)	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1998'	Karen Knapp (b) (4)	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1998'	System	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1998'	System	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1998'	System	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1998'	System	06 Sep 2020 19:37:50

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 05:35:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 05:35:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
Data point term sent to Coder	System	06 Sep 2020 19:39:35
User entered 'NECK VERTEBRATE INFUSION'	Karen Knapp (b) (4)	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1995'	Karen Knapp (b) (4)	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1995'	Karen Knapp (b) (4)	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1995'	System	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1995'	System	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1995'	System	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1995'	System	06 Sep 2020 19:38:49

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Nerve injuries NEC, PT: Nerve injury, LLT: Nerve damage - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:45:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:45:41
Data point term sent to Coder	System	06 Sep 2020 19:39:35
User entered 'NERVE DAMAGE IN NECK'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1995'	Karen Knapp (b) (4)	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1995'	Karen Knapp (b) (4)	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1995'	System	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1995'	System	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1995'	System	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1995'	System	06 Sep 2020 19:39:20

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Seasonal asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:41:38
Data point term sent to Coder	System	06 Sep 2020 19:40:35
User entered 'SEASONAL ASTHMA'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2015'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2015'	System	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2015'	System	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:39:35

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
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) (b) (4)	06 Sep 2020 19:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:41:38
Data point term sent to Coder	System	06 Sep 2020 19:40:36
User entered 'SEASONAL ALLERGIES'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2015'	Karen Knapp (b) (4)	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2015'	System	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2015'	System	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:39:53

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:41:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:41:38
Data point term sent to Coder	System	06 Sep 2020 19:40:35
User entered 'POST MENOPAUSAL'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1973'	Karen Knapp (b) (4)	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1973'	System	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1973'	System	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:40:12

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:42:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 19:42:38
Data point term sent to Coder	System	06 Sep 2020 19:41:37
User entered 'BILATERAL EYES CATARACTS'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2018'	Karen Knapp (b) (4)	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2018'	Karen Knapp (b) (4)	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	06 Sep 2020 19:40:36

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:22:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:22:44
Data point term sent to Coder	System	06 Sep 2020 19:41:36
User entered 'BILATERAL EYES CATARACT SURERY'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2018'	Karen Knapp (b) (4)	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 2018'	Karen Knapp (b) (4)	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	06 Sep 2020 19:41:02

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User closed query 'Per MM, please consider recoding to SOC: Immune system disorders HLGT: Allergic conditions HLT: Allergies to foods, food additives, drugs and other chemicals PT: Drug hypersensitivity LLT: Penicillin allergy' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:21:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 00:01:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 00:01:42
Data point term sent to Coder	System	05 Oct 2020 00:01:28
Query 'Per MM, please consider recoding to SOC: Immune system disorders HLGT: Allergic conditions HLT: Allergies to foods, food additives, drugs and other chemicals PT: Drug hypersensitivity LLT: Penicillin allergy' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:00:48
Coding entries removed.	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:00:44
User entered 'PENICILLIN ALLERGY' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:00:44
User opened query 'Per MM, please consider recoding to SOC: Immune system disorders HLGT: Allergic conditions HLT: Allergies to foods, food additives, drugs and other chemicals PT: Drug hypersensitivity LLT: Penicillin allergy' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:00:17

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 19:42:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 19:42:38
Data point term sent to Coder	System	06 Sep 2020 19:41:37
User entered 'PENICILLIN ALLERGY HIVES'	Karen Knapp (b) (4)	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1960'	Karen Knapp (b) (4)	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1960'	System	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1960'	System	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:41:31

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:02
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:17:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 05:17:43
Data point term sent to Coder	System	06 Sep 2020 19:42:38
User entered 'ALCOHOL USE 3-4 WEEK'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'UN UNK 1966'	Karen Knapp (b) (4)	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:02
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1966'	System	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1966'	System	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	06 Sep 2020 19:41:55

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User closed query 'Per CDM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:16:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
Query 'Per CDM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	19 Feb 2021 20:20:42
User opened query 'Per CDM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 03:56:46
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:44:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:44:10
Data point term sent to Coder	System	03 Dec 2020 19:43:04
User entered 'GLAUCOMA'	Breanna Galibert (b) (4)	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	03 Dec 2020 19:42:20

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Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	03 Dec 2020 19:42:20

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Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:42:20

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease stage 3 - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 04:00:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 04:00:58
Data point term sent to Coder	System	03 Dec 2020 19:44:05
User entered 'BENIGN HYPERTENSION WITH CHRONIC KIDNEY DISEASE TYPE 3'	Breanna Galibert (b) (4) (b) (4)	03 Dec 2020 19:43:27

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Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN Jan 2017'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2017'	System	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2017'	System	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:43:27

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	03 Dec 2020 19:44:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:44:58
	(b) (4)	
Data point term sent to Coder	System	03 Dec 2020 19:44:05
User entered 'OBSTRUCTIVE SLEEP APNEA'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:43
	(b) (4)	

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN Jun 2020'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jun 2020'	System	03 Dec 2020 19:43:43

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Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2020'	System	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:43:43

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Degenerative joint disease - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:44:58
Data point term sent to Coder	(b) (4)	
User entered 'DEGENERATIVE JOINT DISEASE'	System	03 Dec 2020 19:44:06
	Breanna Galibert (b) (4)	03 Dec 2020 19:44:03
	(b) (4)	

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2009'	System	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2009'	System	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:44:03

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Dec 2020 19:46:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:46:13
Data point term sent to Coder	System	03 Dec 2020 19:45:07
User entered 'LEFT KNEE REPLACEMENT'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2009'	System	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2009'	System	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2009'	System	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2009'	System	03 Dec 2020 19:44:18

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:46:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:46:13
Data point term sent to Coder	System	03 Dec 2020 19:45:07
User entered 'OSTEOARTHRITIS BILATERAL KNEES'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2009'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2009'	System	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2009'	System	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2009'	System	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2009'	System	03 Dec 2020 19:44:44

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:46:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:46:13
Data point term sent to Coder	System	03 Dec 2020 19:45:10
User entered 'INSOMNIA'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN Jun 2020'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jun 2020'	System	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2020'	System	03 Dec 2020 19:45:01

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Dec 2020 19:47:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:47:03
Data point term sent to Coder	System	03 Dec 2020 19:46:11
User entered 'HYSTERECTOMY'	Breanna Galibert (b) (4) (b) (4)	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2002'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2002'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2002'	System	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2002'	System	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2002'	System	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2002'	System	03 Dec 2020 19:45:18

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Fibroids - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:47:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:47:03
Data point term sent to Coder	System	03 Dec 2020 19:46:11
User entered 'FIBROIDS'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2002'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2002'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2002'	System	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2002'	System	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2002'	System	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (25)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2002'	System	03 Dec 2020 19:45:34

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Hearing aid user, LLT: Hearing aid user - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:47:03
Data point term sent to Coder	(b) (4)	
User entered 'BILATERAL HEARING AIDS'	System	03 Dec 2020 19:46:11
	Breanna Galibert (b) (4)	03 Dec 2020 19:45:48
	(b) (4)	

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (26)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:45:48

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	03 Dec 2020 19:47:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:47:03
	(b) (4)	
Data point term sent to Coder	System	03 Dec 2020 19:46:11
User entered 'BILATERAL HEARING LOSS'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:03
	(b) (4)	

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2018'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2018'	System	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2018'	System	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (27)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:46:03

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Dec 2020 19:48:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 19:48:12
Data point term sent to Coder	System	03 Dec 2020 19:47:12
User entered 'HYPERLIPIDEMIA'	Breanna Galibert (b) (4) (b) (4)	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2017'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2017'	System	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2017'	System	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (28)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:46:19

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Gastrointestinal disorders, HLG: 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)	03 Dec 2020 19:49:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:49:03
Data point term sent to Coder	System	03 Dec 2020 19:48:13
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2017'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2017'	System	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2017'	System	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (29)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:47:18

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	10 Dec 2020 22:17:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 22:17:09
Data point term sent to Coder	System	03 Dec 2020 19:48:13
User entered 'RIGHT LEFT SCIATICA'	Breanna Galibert (b) (4) (b) (4)	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN Aug 2010'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Aug 2010'	System	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2010'	System	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (30)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 19:47:41

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Investigations, HLGT: Musculoskeletal and soft tissue investigations (excl enzyme tests), HLT: Musculoskeletal and soft tissue imaging procedures, PT: Arthroscopy, LLT: Arthroscopy L knee - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 19:49:07
Data point term sent to Coder	(b) (4)	
User entered 'LEFT KNEE ARTHOSCOPY'	System	03 Dec 2020 19:48:14
	Breanna Galibert (b) (4)	03 Dec 2020 19:48:11
	(b) (4)	

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2000'	System	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2000'	System	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2000'	System	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (31)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2000'	System	03 Dec 2020 19:48:11

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 14:11:50
Data point term sent to Coder	(b) (4)	
User entered 'LEFT KNEE ACL TEAR X2'	System	03 Dec 2020 19:49:15
	Breanna Galibert (b) (4)	03 Dec 2020 19:48:31
	(b) (4)	

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN UNK 2000'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2000'	System	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2000'	System	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2000'	System	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (32)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2000'	System	03 Dec 2020 19:48:31

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's esophagus - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 20:02:29
Data point term sent to Coder	(b) (4)	
User entered 'BARRETS ESOPHAGUS'	System	03 Dec 2020 20:01:28
	Breanna Galibert (b) (4)	03 Dec 2020 20:01:03
	(b) (4)	

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'UN Aug 2017'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Aug 2017'	System	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2017'	System	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (33)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:01:03

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Dec 2020 20:02:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:02:28
Data point term sent to Coder	System	03 Dec 2020 20:01:28
User entered 'osteopenia'	Breanna Galibert (b) (4) (b) (4)	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'un UNK 2010'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2010'	System	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2010'	System	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (34)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:01:19

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 20:03:05
Data point term sent to Coder	(b) (4)	
User entered 'constipation'	Coder Import (b) (4)	03 Dec 2020 20:03:05
	(b) (4)	
	System	03 Dec 2020 20:02:29
	Breanna Galibert (b) (4)	03 Dec 2020 20:01:43
	(b) (4)	

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'un UNK 1945'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 1945'	System	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '1945'	System	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (35)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:01:43

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Bunion operation, LLT: Bunionectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Dec 2020 20:03:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:03:05
Data point term sent to Coder	System	03 Dec 2020 20:02:30
User entered 'bilateral bunionectomy'	Breanna Galibert (b) (4) (b) (4)	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'un UNK 2013'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'un UNK 2013'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2013'	System	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2013'	System	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2013'	System	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (36)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2013'	System	03 Dec 2020 20:02:14

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Extremity deformities, PT: Foot deformity, LLT: Bunion - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 20:05:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 20:05:03
Data point term sent to Coder	System	03 Dec 2020 20:03:32
User entered 'bilateral bunions'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'un UNK 2013'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'un UNK 2013'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2013'	System	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2013'	System	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2013'	System	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (37)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2013'	System	03 Dec 2020 20:02:31

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Dec 2020 20:05:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 20:05:01
Data point term sent to Coder	System	03 Dec 2020 20:03:30
User entered 'vitamin d deficiency'	Breanna Galibert (b) (4) (b) (4)	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'un UNK 2017'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Breanna Galibert (b) (4)	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:11:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Breanna Galibert (b) (4)	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'Jan 2017'	System	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '2017'	System	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Medical History (38)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered empty.	System	03 Dec 2020 20:02:50

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:33
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:33
User entered '21 Aug 2020'	Karen Knapp (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:33
User entered '08:13'	Karen Knapp (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '21 Aug 2020 08:13'	System	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:33
User entered '65' in	Karen Knapp (b) (4)	06 Sep 2020 19:42:34
DataPoint set to visible.	System	21 Aug 2020 15:13:27

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:33
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Sep 2020 19:43:04
User entered '190.4' lb reason for change: Data Entry Karen Knapp Error	(b) (4)	06 Sep 2020 19:43:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Sep 2020 19:42:34
User entered '190.' (non-conformant).	Karen Knapp (b) (4)	06 Sep 2020 19:42:34
DataPoint set to visible.	(b) (4) System	21 Aug 2020 15:13:27

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered '31.75047'	System	06 Sep 2020 19:43:04
User entered empty.	System	06 Sep 2020 19:42:34
DataPoint set to visible.	System	21 Aug 2020 15:13:27

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'kg/m2'	System	06 Sep 2020 19:43:04
User entered empty.	System	06 Sep 2020 19:42:34
DataPoint set to visible.	System	21 Aug 2020 15:13:27

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:33
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 09:45:52
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Angie Kean (b) (4) (b) (4)	04 Oct 2020 23:59:50
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:17:49
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:43:04
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	06 Sep 2020 19:43:04
User entered '96' F reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:43:04
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:42:34
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:33
User entered 'Oral (Oral)' reason for change: Data Entry Error	Karen Knapp (b) (4)	06 Sep 2020 19:43:04
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:39:33
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:33
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:43:04
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	06 Sep 2020 19:43:04
User entered '66' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:43:04
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:42:34
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'bpm'	System	06 Sep 2020 19:43:04
User entered empty.	System	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:33
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:43:04
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	06 Sep 2020 19:43:04
User entered '16' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:43:04
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:42:34
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'breaths/min'	System	06 Sep 2020 19:43:04
User entered empty.	System	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:33
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:43:04
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	06 Sep 2020 19:43:04
User entered '130' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:43:04
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:42:34
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'mmHg'	System	06 Sep 2020 19:43:04
User entered empty.	System	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:39:33
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:43:04
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	06 Sep 2020 19:43:04
User entered '72' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:43:04
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Sep 2020 19:42:34
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User entered 'mmHg'	System	06 Sep 2020 19:43:04
User entered empty.	System	06 Sep 2020 19:42:34

US3812229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35

US3812229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:29
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:43:20

US3812229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:40:29
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	06 Sep 2020 19:43:29
User entered '21 Aug 2020' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:43:29
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	06 Sep 2020 19:43:20
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:43:20

US3812229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:06
User entered '21 Aug 2020'	Karen Knapp (b) (4)	06 Sep 2020 19:44:06

US3812229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:06
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:44:06

US3812229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:34:06
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 09:57:13
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' answered with 'UPDATED PER QUERY ' (Site from DM).	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:01:57
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 06:10:46
User entered 'Surgically sterile (SURGICALLY STERILE)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:06

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:06
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:44:06

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:06
User entered 'UN UNK 1970'	Karen Knapp (b) (4)	06 Sep 2020 19:44:06

US3812229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:06
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:44:06

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:06
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:44:06

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:52:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:34:06
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:44:06

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

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[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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

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Generated On: 10 Jun 2021 09:52:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:45:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:45:17
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:45:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:44:58
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered '0'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

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)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'I'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:09:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:33:22
User entered 'SOCIAL BEHAVIOR, LARGE GROUP EVENTS'	Karen Knapp (b) (4)	06 Sep 2020 19:44:58

US3812229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:08
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:13:43

US3812229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:08
User entered '21 Aug 2020'	Heather Cherniawski (b) (4)	21 Aug 2020 15:13:43

US3812229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:32:08
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:13:43

US3812229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'VISIT1'	System	21 Aug 2020 15:13:43

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:19:28

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered '186981'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:19:28

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:19:28

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

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)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:11
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4)	11 Sep 2020 18:33:26
Query 'PER CDM: Please complete this section of the form.' answered with 'COMPLETED' (Site from DM).	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:34:32
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:33:55
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:11:42

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

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)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:33:55

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:33:55

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:33:55

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:33:55

US3812229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:11
User entered 'No (N)'	Heather Cherniawski (b) (4)	29 Oct 2020 20:40:17
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:56:51

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '65' in	Karen Knapp (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '190.4' lb	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '65' in	Karen Knapp (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '190.4' lb	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '21 Aug 2020'	Karen Knapp (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '08:13'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered '21 Aug 2020 08:13'	System	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 10:50:12
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Angie Kean (b) (4) (b) (4)	04 Oct 2020 23:59:23
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:17:49
User entered '96' F	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '66'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'bpm'	System	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '16'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'breaths/min'	System	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '130'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'mmHg'	System	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '72'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'mmHg'	System	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '65' in	Karen Knapp (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '190.4' lb	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:01

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '21 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '10:11'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered '21 Aug 2020 10:11'	System	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '97.2' F	Karen Knapp (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered 'Oral (Oral)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '65'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'bpm'	System	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '13'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'breaths/min'	System	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '128'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'mmHg'	System	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:44:44
User entered '68'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'mmHg'	System	06 Sep 2020 19:47:49

US3812229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:40:02
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4) (b) (4)	16 Sep 2020 23:56:33
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:04

US3812229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:40:02
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 23:56:33
User entered '21 Aug 2020'	Karen Knapp (b) (4)	06 Sep 2020 19:48:04

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:42:13
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:42:13
User entered empty.	Heather Cherniawski (b) (4)	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

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)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:42:13
User entered empty.	Heather Cherniawski (b) (4)	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:42:13
User entered '21 Aug 2020'	Heather Cherniawski (b) (4)	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:42:13
User entered '09:38'	Heather Cherniawski (b) (4)	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered '21 Aug 2020 09:38'	System	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:42:13
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski (b) (4)	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:42:13
User entered 'ONCE'	System	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 15:14:11

US3812229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:23
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:34

US3812229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:41:23
User entered '21 Aug 2020'	Karen Knapp (b) (4)	06 Sep 2020 19:48:34

US3812229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:23
User entered '09:20'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:34

US3812229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered '21 Aug 2020 09:20'	System	06 Sep 2020 19:48:34

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:52:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:32
User entered '21 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:32
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:32
User entered '09:23'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered '21 Aug 2020 09:23'	System	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:32
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:41:32
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered empty.	System	06 Sep 2020 19:48:49

US3812229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:42:19
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:48:54

US3812229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'I'	System	06 Sep 2020 19:48:54

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:17:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a2b3ace8-6ac3-4ee6-95fa-fb645e635a1c' User entered 'Yes (Y)'	System	21 Aug 2020 15:18:31
	System	21 Aug 2020 15:18:31

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:18:22', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a2b3ace8-6ac3-4ee6-95fa-fb645e635a1c' User entered '97.2'	System	21 Aug 2020 15:18:31
	System	21 Aug 2020 15:18:31

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:18:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a2b3ace8-6ac3-4ee6-95fa-fb645e635a1c' User entered 'No (N)'	System	21 Aug 2020 15:18:31
	System	21 Aug 2020 15:18:31

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:18:27', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a2b3ace8-6ac3-4ee6-95fa-fb645e635a1c' User entered '21 Aug 2020 10:18'	System	21 Aug 2020 15:18:31
	System	21 Aug 2020 15:18:31

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 09:58'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 12:28'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:46:11', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dfb6b71e-5e28-45fe-bcb7-b8a6527b41bb' User entered 'Yes (Y)'	System	21 Aug 2020 18:47:09
	System	21 Aug 2020 18:47:09

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:46:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dfb6b71e-5e28-45fe-bcb7-b8a6527b41bb' User entered '96.5'	System	21 Aug 2020 18:47:09
	System	21 Aug 2020 18:47:09

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:46:46', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dfb6b71e-5e28-45fe-bcb7-b8a6527b41bb' User entered 'No (N)'	System	21 Aug 2020 18:47:09
	System	21 Aug 2020 18:47:09

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:47:06', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dfb6b71e-5e28-45fe-bcb7-b8a6527b41bb' User entered '21 Aug 2020 13:47'	System	21 Aug 2020 18:47:09
	System	21 Aug 2020 18:47:09

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 13:23'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 2'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:12:59', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'eb17a27d-d366-4745-9c8a-fe6f701095fd' User entered 'Yes (Y)'	System	22 Aug 2020 17:13:23
	System	22 Aug 2020 17:13:23

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:12:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'eb17a27d-d366-4745-9c8a-fe6f701095fd' User entered '96.5'	System	22 Aug 2020 17:13:23
	System	22 Aug 2020 17:13:23

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:12:50', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'eb17a27d-d366-4745-9c8a-fe6f701095fd' User entered 'No (N)'	System	22 Aug 2020 17:13:23
	System	22 Aug 2020 17:13:23

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:13:20', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'eb17a27d-d366-4745-9c8a-fe6f701095fd' User entered '22 Aug 2020 12:13'	System	22 Aug 2020 17:13:23
	System	22 Aug 2020 17:13:23

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 3'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:25:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0574c4d2-96de-40a8-bd6e-a92308b81851' User entered 'Yes (Y)'	System	23 Aug 2020 19:26:39
	System	23 Aug 2020 19:26:39

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:26:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0574c4d2-96de-40a8-bd6e-a92308b81851' User entered '97.3'	System	23 Aug 2020 19:26:39
	System	23 Aug 2020 19:26:39

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:26:13', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0574c4d2-96de-40a8-bd6e-a92308b81851'	System	23 Aug 2020 19:26:39
User entered 'No (N)'	System	23 Aug 2020 19:26:39

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:26:36', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0574c4d2-96de-40a8-bd6e-a92308b81851' User entered '23 Aug 2020 14:26'	System	23 Aug 2020 19:26:39
	System	23 Aug 2020 19:26:39

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 4'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:00:31', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1c4aa94d-408a-4c02-95ed-1c0788d62612' User entered 'Yes (Y)'	System	24 Aug 2020 17:01:16
	System	24 Aug 2020 17:01:16

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:00:45', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1c4aa94d-408a-4c02-95ed-1c0788d62612' User entered '97.4'	System	24 Aug 2020 17:01:16
	System	24 Aug 2020 17:01:16

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:00:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1c4aa94d-408a-4c02-95ed-1c0788d62612'	System	24 Aug 2020 17:01:16
User entered 'No (N)'	System	24 Aug 2020 17:01:16

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:01:04', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1c4aa94d-408a-4c02-95ed-1c0788d62612' User entered '24 Aug 2020 12:01'	System	24 Aug 2020 17:01:16
	System	24 Aug 2020 17:01:16

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 5'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:05:16', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '552f6f8d-508a-4a49-8080-706fa4efb0da' User entered 'Yes (Y)'	System	26 Aug 2020 00:05:29
	System	26 Aug 2020 00:05:29

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:04:56', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '552f6f8d-508a-4a49-8080-706fa4efb0da' User entered '98.0'	System	26 Aug 2020 00:05:29
	System	26 Aug 2020 00:05:29

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:05:10', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '552f6f8d-508a-4a49-8080-706fa4efb0da' User entered 'No (N)'	System	26 Aug 2020 00:05:29
	System	26 Aug 2020 00:05:29

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:05:27', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '552f6f8d-508a-4a49-8080-706fa4efb0da' User entered '25 Aug 2020 19:05'	System	26 Aug 2020 00:05:29
	System	26 Aug 2020 00:05:29

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 6'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:42:12', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c013e34f-e13e-417c-bd1f-0955a66dfa91' User entered 'Yes (Y)'	System	26 Aug 2020 19:43:45
	System	26 Aug 2020 19:43:45

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:43:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c013e34f-e13e-417c-bd1f-0955a66dfa91' User entered '96.5'	System	26 Aug 2020 19:43:45
	System	26 Aug 2020 19:43:45

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:43:35', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c013e34f-e13e-417c-bd1f-0955a66dfa91'	System	26 Aug 2020 19:43:45
User entered 'No (N)'	System	26 Aug 2020 19:43:45

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:43:43', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c013e34f-e13e-417c-bd1f-0955a66dfa91' User entered '26 Aug 2020 14:43'	System	26 Aug 2020 19:43:45
	System	26 Aug 2020 19:43:45

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 7'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:39:40', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8f411937-3af9-4944-99a5-efb3b4f4a638'	System	27 Aug 2020 20:40:18
User entered 'Yes (Y)'	System	27 Aug 2020 20:40:18

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:39:55', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8f411937-3af9-4944-99a5-efb3b4f4a638'	System	27 Aug 2020 20:40:18
User entered '97.5'	System	27 Aug 2020 20:40:18

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:40:05', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8f411937-3af9-4944-99a5-efb3b4f4a638'	System	27 Aug 2020 20:40:18
User entered 'No (N)'	System	27 Aug 2020 20:40:18

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:40:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8f411937-3af9-4944-99a5-efb3b4f4a638'	System	27 Aug 2020 20:40:18
User entered '27 Aug 2020 15:40'	System	27 Aug 2020 20:40:18

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:18:51', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3d648dd6-5e95-41ea-a80c-dbf04bd94cce' User entered 'None (1)'	System	21 Aug 2020 15:19:40
	System	21 Aug 2020 15:19:40

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:19:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3d648dd6-5e95-41ea-a80c-dbf04bd94cce' User entered 'No (N)'	System	21 Aug 2020 15:19:40
	System	21 Aug 2020 15:19:40

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:19:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3d648dd6-5e95-41ea-a80c-dbf04bd94cce' User entered 'No (N)'	System	21 Aug 2020 15:19:40
	System	21 Aug 2020 15:19:40

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:19:27', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3d648dd6-5e95-41ea-a80c-dbf04bd94cce' User entered 'None (1)'	System	21 Aug 2020 15:19:40
	System	21 Aug 2020 15:19:40

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:19:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3d648dd6-5e95-41ea-a80c-dbf04bd94cce' User entered '21 Aug 2020 10:19'	System	21 Aug 2020 15:19:40
	System	21 Aug 2020 15:19:40

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 09:58'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 12:28'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:49:46', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd264012c-b95e-45c8-aae7-c48c3e6b9a83'	System	21 Aug 2020 18:51:33
User entered 'None (1)'	System	21 Aug 2020 18:51:33

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:49:55', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd264012c-b95e-45c8-aae7-c48c3e6b9a83'	System	21 Aug 2020 18:51:33
User entered 'No (N)'	System	21 Aug 2020 18:51:33

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:51:10', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd264012c-b95e-45c8-aae7-c48c3e6b9a83'	System	21 Aug 2020 18:51:33
User entered 'No (N)'	System	21 Aug 2020 18:51:33

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:51:16', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd264012c-b95e-45c8-aae7-c48c3e6b9a83'	System	21 Aug 2020 18:51:33
User entered 'None (1)'	System	21 Aug 2020 18:51:33

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:51:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd264012c-b95e-45c8-aae7-c48c3e6b9a83' User entered '21 Aug 2020 13:51'	System	21 Aug 2020 18:51:33
	System	21 Aug 2020 18:51:33

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 13:23'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 2'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:47', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b34bb44a-73e3-4d02-8451-ded7cd03c274'	System	22 Aug 2020 17:15:11
User entered 'None (1)'	System	22 Aug 2020 17:15:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:53', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b34bb44a-73e3-4d02-8451-ded7cd03c274' User entered 'No (N)'	System	22 Aug 2020 17:15:11
	System	22 Aug 2020 17:15:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:57', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b34bb44a-73e3-4d02-8451-ded7cd03c274' User entered 'No (N)'	System	22 Aug 2020 17:15:11
	System	22 Aug 2020 17:15:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:15:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b34bb44a-73e3-4d02-8451-ded7cd03c274' User entered 'None (1)'	System	22 Aug 2020 17:15:11
	System	22 Aug 2020 17:15:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:15:08', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b34bb44a-73e3-4d02-8451-ded7cd03c274' User entered '22 Aug 2020 12:15'	System	22 Aug 2020 17:15:11
	System	22 Aug 2020 17:15:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 3'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:26:52', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8dc488ba-1884-4cf3-8f7e-85664f021a90'	System	23 Aug 2020 19:28:16
User entered 'None (1)'	System	23 Aug 2020 19:28:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:27:32', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8dc488ba-1884-4cf3-8f7e-85664f021a90' User entered 'No (N)'	System	23 Aug 2020 19:28:16
	System	23 Aug 2020 19:28:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:27:44', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8dc488ba-1884-4cf3-8f7e-85664f021a90' User entered 'No (N)'	System	23 Aug 2020 19:28:16
	System	23 Aug 2020 19:28:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:27:59', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8dc488ba-1884-4cf3-8f7e-85664f021a90'	System	23 Aug 2020 19:28:16
User entered 'None (1)'	System	23 Aug 2020 19:28:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:28:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8dc488ba-1884-4cf3-8f7e-85664f021a90' User entered '23 Aug 2020 14:28'	System	23 Aug 2020 19:28:16
	System	23 Aug 2020 19:28:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 4'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:01:24', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '289d3e90-590c-4c0a-b950-ee8962c2e642'	System	24 Aug 2020 17:01:55
User entered 'None (1)'	System	24 Aug 2020 17:01:55

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:01:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '289d3e90-590c-4c0a-b950-ee8962c2e642'	System	24 Aug 2020 17:01:55
User entered 'No (N)'	System	24 Aug 2020 17:01:55

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:01:33', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '289d3e90-590c-4c0a-b950-ee8962c2e642' User entered 'No (N)'	System	24 Aug 2020 17:01:55
	System	24 Aug 2020 17:01:55

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:01:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '289d3e90-590c-4c0a-b950-ee8962c2e642'	System	24 Aug 2020 17:01:55
User entered 'None (1)'	System	24 Aug 2020 17:01:55

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:01:45', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '289d3e90-590c-4c0a-b950-ee8962c2e642' User entered '24 Aug 2020 12:01'	System	24 Aug 2020 17:01:55
	System	24 Aug 2020 17:01:55

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 5'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:07:18', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e39f7ec-1b23-423e-8b91-a28a142376b3'	System	26 Aug 2020 00:08:16
User entered 'None (1)'	System	26 Aug 2020 00:08:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:07:23', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e39f7ec-1b23-423e-8b91-a28a142376b3'	System	26 Aug 2020 00:08:16
User entered 'No (N)'	System	26 Aug 2020 00:08:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:07:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e39f7ec-1b23-423e-8b91-a28a142376b3'	System	26 Aug 2020 00:08:16
User entered 'No (N)'	System	26 Aug 2020 00:08:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:08:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e39f7ec-1b23-423e-8b91-a28a142376b3'	System	26 Aug 2020 00:08:16
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 00:08:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:08:12', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e39f7ec-1b23-423e-8b91-a28a142376b3' User entered '25 Aug 2020 19:08'	System	26 Aug 2020 00:08:16
	System	26 Aug 2020 00:08:16

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 6'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:44:04', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f8745534-4fea-421c-b16b-415f6d609424'	System	26 Aug 2020 19:44:38
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 19:44:38

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:44:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f8745534-4fea-421c-b16b-415f6d609424' User entered 'No (N)'	System	26 Aug 2020 19:44:38
	System	26 Aug 2020 19:44:38

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:44:20', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f8745534-4fea-421c-b16b-415f6d609424' User entered 'No (N)'	System	26 Aug 2020 19:44:38
	System	26 Aug 2020 19:44:38

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:44:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f8745534-4fea-421c-b16b-415f6d609424' User entered 'None (1)'	System	26 Aug 2020 19:44:38
	System	26 Aug 2020 19:44:38

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:44:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f8745534-4fea-421c-b16b-415f6d609424' User entered '26 Aug 2020 14:44'	System	26 Aug 2020 19:44:38
	System	26 Aug 2020 19:44:38

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 7'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:40:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c16bfba8-9945-48f5-aa04-d1a95dd673a1' User entered 'None (1)'	System	27 Aug 2020 20:41:13
	System	27 Aug 2020 20:41:13

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:40:46', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c16bfba8-9945-48f5-aa04-d1a95dd673a1' User entered 'No (N)'	System	27 Aug 2020 20:41:13
	System	27 Aug 2020 20:41:13

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:40:50', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c16bfba8-9945-48f5-aa04-d1a95dd673a1' User entered 'No (N)'	System	27 Aug 2020 20:41:13
	System	27 Aug 2020 20:41:13

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:40:57', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c16bfba8-9945-48f5-aa04-d1a95dd673a1' User entered 'None (1)'	System	27 Aug 2020 20:41:13
	System	27 Aug 2020 20:41:13

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:09', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'c16bfba8-9945-48f5-aa04-d1a95dd673a1' User entered '27 Aug 2020 15:41'	System	27 Aug 2020 20:41:13
	System	27 Aug 2020 20:41:13

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered 'None (0)'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered 'None (0)'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered 'None (0)'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:11', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered 'None (0)'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:14', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered 'None (0)'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered 'None (0)'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:24', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered 'No (N)'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T10:20:45', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a6624ad1-7089-41ed-9cb8-2b1f718e3b5f' User entered '21 Aug 2020 10:20'	System	21 Aug 2020 15:20:51
	System	21 Aug 2020 15:20:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 09:58'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 12:28'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:48:14', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122' User entered 'None (0)'	System	21 Aug 2020 18:49:17
	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:48:25', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122'	System	21 Aug 2020 18:49:17
User entered 'No interference with activity (1)'	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:48:31', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122' User entered 'None (0)'	System	21 Aug 2020 18:49:17
	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:48:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122' User entered 'None (0)'	System	21 Aug 2020 18:49:17
	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:48:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122' User entered 'None (0)'	System	21 Aug 2020 18:49:17
	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:48:41', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122' User entered 'None (0)'	System	21 Aug 2020 18:49:17
	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:48:49', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122'	System	21 Aug 2020 18:49:17
User entered 'No (N)'	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-21T13:49:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '082f9a87-b6d1-4a49-a5e4-22bbfe83f122'	System	21 Aug 2020 18:49:17
User entered '21 Aug 2020 13:49'	System	21 Aug 2020 18:49:17

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Aug 2020 13:23'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 2'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:13:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d' User entered 'None (0)'	System	22 Aug 2020 17:14:30
	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:13:55', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d'	System	22 Aug 2020 17:14:30
User entered 'No interference with activity (1)'	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d' User entered 'None (0)'	System	22 Aug 2020 17:14:30
	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:05', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d' User entered 'None (0)'	System	22 Aug 2020 17:14:30
	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:10', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d' User entered 'None (0)'	System	22 Aug 2020 17:14:30
	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:13', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d' User entered 'None (0)'	System	22 Aug 2020 17:14:30
	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:20', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d' User entered 'No (N)'	System	22 Aug 2020 17:14:30
	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-22T12:14:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6506ff6-46fd-4639-a3f6-4abcb07fed2d' User entered '22 Aug 2020 12:14'	System	22 Aug 2020 17:14:30
	System	22 Aug 2020 17:14:30

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 3'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:29:18', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff' User entered 'None (0)'	System	23 Aug 2020 19:30:08
	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:29:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff'	System	23 Aug 2020 19:30:08
User entered 'No interference with activity (1)'	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:29:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff' User entered 'None (0)'	System	23 Aug 2020 19:30:08
	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:29:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff' User entered 'None (0)'	System	23 Aug 2020 19:30:08
	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:29:42', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff' User entered 'None (0)'	System	23 Aug 2020 19:30:08
	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:29:46', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff' User entered 'None (0)'	System	23 Aug 2020 19:30:08
	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:29:51', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff'	System	23 Aug 2020 19:30:08
User entered 'No (N)'	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-23T14:30:05', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '53666385-5dfa-4621-b697-f2477f587dff' User entered '23 Aug 2020 14:30'	System	23 Aug 2020 19:30:08
	System	23 Aug 2020 19:30:08

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 4'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:02:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20' User entered 'None (0)'	System	24 Aug 2020 17:03:47
	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:02:16', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20'	System	24 Aug 2020 17:03:47
User entered 'No interference with activity (1)'	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:02:28', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20'	System	24 Aug 2020 17:03:47
User entered 'No interference with activity (1)'	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:02:38', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20'	System	24 Aug 2020 17:03:47
User entered 'No interference with activity (1)'	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:02:58', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20'	System	24 Aug 2020 17:03:47
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:03:06', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20' User entered 'None (0)'	System	24 Aug 2020 17:03:47
	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:03:12', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20' User entered 'No (N)'	System	24 Aug 2020 17:03:47
	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-24T12:03:43', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9b6579b7-58f3-4c1a-9e56-3a10996efd20' User entered '24 Aug 2020 12:03'	System	24 Aug 2020 17:03:47
	System	24 Aug 2020 17:03:47

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 5'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:08:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552'	System	26 Aug 2020 00:09:29
User entered 'No interference with activity (1)'	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:08:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552'	System	26 Aug 2020 00:09:29
User entered 'No interference with activity (1)'	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:08:55', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552' User entered 'None (0)'	System	26 Aug 2020 00:09:29
	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:09:05', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552' User entered 'None (0)'	System	26 Aug 2020 00:09:29
	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:09:10', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552' User entered 'None (0)'	System	26 Aug 2020 00:09:29
	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:09:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552' User entered 'None (0)'	System	26 Aug 2020 00:09:29
	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:09:22', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552'	System	26 Aug 2020 00:09:29
User entered 'No (N)'	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-25T19:09:27', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9dab439d-d961-4691-aef3-16853c89c552'	System	26 Aug 2020 00:09:29
User entered '25 Aug 2020 19:09'	System	26 Aug 2020 00:09:29

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 6'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:12', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered 'None (0)'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered 'None (0)'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered 'None (0)'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered 'None (0)'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered 'None (0)'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:42', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered 'None (0)'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:48', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered 'No (N)'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-26T14:54:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7b4ba0f1-78df-4ba5-8bcf-5008df23a56a' User entered '26 Aug 2020 14:54'	System	26 Aug 2020 19:54:56
	System	26 Aug 2020 19:54:56

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 7'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:19', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178' User entered 'None (0)'	System	27 Aug 2020 20:41:51
	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:23', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178' User entered 'None (0)'	System	27 Aug 2020 20:41:51
	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178' User entered 'None (0)'	System	27 Aug 2020 20:41:51
	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:33', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178' User entered 'None (0)'	System	27 Aug 2020 20:41:51
	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:36', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178' User entered 'None (0)'	System	27 Aug 2020 20:41:51
	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178' User entered 'None (0)'	System	27 Aug 2020 20:41:51
	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:45', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178'	System	27 Aug 2020 20:41:51
User entered 'No (N)'	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-08-27T15:41:49', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fe24b14d-6e0f-4f70-abe3-51bcaac5c178' User entered '27 Aug 2020 15:41'	System	27 Aug 2020 20:41:51
	System	27 Aug 2020 20:41:51

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 15:14:11

US3812229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:35:38
User closed query 'Source indicates that this was a convalescent tele-medicine call, not a safety call. Please review, and move the data as required.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:35:32
Query 'Source indicates that this was a convalescent tele-medicine call, not a safety call. Please review, and move the data as required.' answered with 'Updated' (Site from CRA).	Angie Kean (b) (4) (b) (4)	19 Nov 2020 00:24:26
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	19 Nov 2020 00:24:22
User opened query 'Source indicates that this was a convalescent tele-medicine call, not a safety call. Please review, and move the data as required.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 20:32:55
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:35

US3812229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:35:38
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	19 Nov 2020 00:24:22
User entered '29 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:35

US3812229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:35:38
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	19 Nov 2020 00:24:22
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:35

US3812229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:35:38
User entered 'Subject in convalescent period, no safety call made outside of illness contact' reason for change: New Information	Angie Kean (b) (4) (b) (4)	19 Nov 2020 00:24:22
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:35

US3812229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:35:54
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:40

US3812229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'I'	System	06 Sep 2020 19:49:40

US3812229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:37:24
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:55

US3812229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:37:24
User entered '05 Sep 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4) (b) (4)	10 Nov 2020 23:15:55
User entered '5 Sep 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:55

US3812229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:37:24
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:55

US3812229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:37:24
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:55

US3812229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:37:38
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:49:59

US3812229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:49:53
User entered 'I'	System	06 Sep 2020 19:49:59

US3812229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:38:09
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 19:56:59

US3812229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:38:09
User entered '11 Sep 2020'	Karen Knapp (b) (4)	11 Sep 2020 19:56:59

US3812229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:38:09
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 19:56:59

US3812229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:38:09
User entered empty.	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 19:56:59

US3812229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:19
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:38:34
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 19:57:04

US3812229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:19
User entered 'I'	System	11 Sep 2020 19:57:04

US3812229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:39:25
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:13
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:39:25
User entered '18 Sep 2020'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:13
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:39:25
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:13
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'VISIT2'	System	18 Sep 2020 16:00:13

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '18 Sep 2020'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '10:19'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered '18 Sep 2020 10:19'	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 11:45:38
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	Angie Kean (b) (4)	04 Oct 2020 23:58:11
User entered '96.0' F	(b) (4)	
	System	18 Sep 2020 16:03:41
	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '60'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'bpm'	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'breaths/min'	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '132'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'mmHg'	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '90'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'mmHg'	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '18 Sep 2020'	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:31:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Sep 2020 16:31:08
User entered '11:25' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Sep 2020 16:31:08
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:03:41
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered '18 Sep 2020 11:25'	System	18 Sep 2020 16:31:08
User entered empty.	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 11:45:43
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Angie Kean (b) (4)	04 Oct 2020 23:59:06
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	18 Sep 2020 16:31:44
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Sep 2020 16:31:44
User entered '96.2' F reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Sep 2020 16:31:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Sep 2020 16:31:08
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:31:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Sep 2020 16:31:08
User entered '96.2' (non-conformant).	Breanna Galibert (b) (4)	18 Sep 2020 16:31:08
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:03:41
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Sep 2020 16:31:44
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:31:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Sep 2020 16:31:08
User entered '60' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Sep 2020 16:31:08
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:03:41
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'bpm'	System	18 Sep 2020 16:31:08
User entered empty.	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:31:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Sep 2020 16:31:08
User entered '14' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Sep 2020 16:31:08
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:03:41
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'breaths/min'	System	18 Sep 2020 16:31:08
User entered empty.	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:31:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Sep 2020 16:31:08
User entered '130' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Sep 2020 16:31:08
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:03:41
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'mmHg'	System	18 Sep 2020 16:31:08
User entered empty.	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:39:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:31:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Sep 2020 16:31:08
User entered '90' reason for change: Data Entry Error	Breanna Galibert (b) (4)	18 Sep 2020 16:31:08
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 16:03:41
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:03:41
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'mmHg'	System	18 Sep 2020 16:31:08
User entered empty.	System	18 Sep 2020 16:03:41

US3812229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:01
User entered 'No (N)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:31
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:01
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:00:31
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:21
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Sep 2020 16:01:19
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:21
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:01:19
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:21
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:01:19
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:01:19

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 20:40:21
User entered '18 Sep 2020'	Breanna Galibert (b) (4)	18 Sep 2020 16:01:19
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 20:40:21
User entered '10:43'	Breanna Galibert (b) (4)	18 Sep 2020 16:01:19
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered '18 Sep 2020 10:43'	System	18 Sep 2020 16:01:19

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:21
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	18 Sep 2020 16:01:19
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:21
User entered 'ONCE'	System	18 Sep 2020 16:01:19

US3812229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:01:19

US3812229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 20:42:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:45
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 20:42:00
User entered '18 Sep 2020'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:45
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:42:00
User entered '10:35'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:45
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered '18 Sep 2020 10:35'	System	18 Sep 2020 16:00:45

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:37
User entered '18 Sep 2020'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:57
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:57
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:37
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:57
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:37
User entered '10:40'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:57
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered '18 Sep 2020 10:40'	System	18 Sep 2020 16:00:57

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:57
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:37
User entered 'No (N)'	Breanna Galibert (b) (4)	18 Sep 2020 16:00:57
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:40:37
User entered empty.	Breanna Galibert (b) (4)	18 Sep 2020 16:00:57
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered empty.	System	18 Sep 2020 16:00:57

US3812229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:41:36
User entered 'Yes (Y)'	Karen Knapp (b) (4)	26 Sep 2020 17:13:18
	(b) (4)	

US3812229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'I'	System	26 Sep 2020 17:13:18

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:22:35', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'acfdd004-9886-4f2e-a3ed-04c5f706b290' User entered 'Yes (Y)'	System	18 Sep 2020 16:23:01
	System	18 Sep 2020 16:23:01

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:22:47', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'acfdd004-9886-4f2e-a3ed-04c5f706b290' User entered '96.2'	System	18 Sep 2020 16:23:01
	System	18 Sep 2020 16:23:01

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:22:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'acfdd004-9886-4f2e-a3ed-04c5f706b290'	System	18 Sep 2020 16:23:01
User entered 'No (N)'	System	18 Sep 2020 16:23:01

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:22:58', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'acfdd004-9886-4f2e-a3ed-04c5f706b290' User entered '18 Sep 2020 11:22'	System	18 Sep 2020 16:23:01
	System	18 Sep 2020 16:23:01

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 11:03'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 13:33'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:49:45', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '59802095-0c90-410e-9f29-29bc4e15a4e6' User entered 'Yes (Y)'	System	19 Sep 2020 14:50:00
	System	19 Sep 2020 14:50:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:49:28', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '59802095-0c90-410e-9f29-29bc4e15a4e6' User entered '95.4'	System	19 Sep 2020 14:50:00
	System	19 Sep 2020 14:50:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:49:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '59802095-0c90-410e-9f29-29bc4e15a4e6' User entered 'No (N)'	System	19 Sep 2020 14:50:00
	System	19 Sep 2020 14:50:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:49:58', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '59802095-0c90-410e-9f29-29bc4e15a4e6' User entered '19 Sep 2020 09:49'	System	19 Sep 2020 14:50:00
	System	19 Sep 2020 14:50:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 14:28'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 2'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:03:16', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b7a32a17-6710-4d43-bf71-4d80d162679d' User entered 'Yes (Y)'	System	19 Sep 2020 17:03:53
	System	19 Sep 2020 17:03:53

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:03:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b7a32a17-6710-4d43-bf71-4d80d162679d' User entered '97.0'	System	19 Sep 2020 17:03:53
	System	19 Sep 2020 17:03:53

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:03:41', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b7a32a17-6710-4d43-bf71-4d80d162679d' User entered 'No (N)'	System	19 Sep 2020 17:03:53
	System	19 Sep 2020 17:03:53

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:03:51', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b7a32a17-6710-4d43-bf71-4d80d162679d' User entered '19 Sep 2020 12:03'	System	19 Sep 2020 17:03:53
	System	19 Sep 2020 17:03:53

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 3'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:11', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b2e2b360-c346-4458-ac0b-8782f34b84d3' User entered 'Yes (Y)'	System	21 Sep 2020 14:16:31
	System	21 Sep 2020 14:16:31

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:14:53', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b2e2b360-c346-4458-ac0b-8782f34b84d3' User entered '94.8'	System	21 Sep 2020 14:16:31
	System	21 Sep 2020 14:16:31

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b2e2b360-c346-4458-ac0b-8782f34b84d3' User entered 'No (N)'	System	21 Sep 2020 14:16:31
	System	21 Sep 2020 14:16:31

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:16', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b2e2b360-c346-4458-ac0b-8782f34b84d3' User entered '21 Sep 2020 09:15'	System	21 Sep 2020 14:16:31
	System	21 Sep 2020 14:16:31

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 4'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:10:58', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9f65b88f-b62c-4472-a062-dc71d7703bde' User entered 'Yes (Y)'	System	22 Sep 2020 03:11:44
	System	22 Sep 2020 03:11:44

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:11:20', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9f65b88f-b62c-4472-a062-dc71d7703bde' User entered '97.1'	System	22 Sep 2020 03:11:44
	System	22 Sep 2020 03:11:44

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:11:31', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9f65b88f-b62c-4472-a062-dc71d7703bde' User entered 'No (N)'	System	22 Sep 2020 03:11:44
	System	22 Sep 2020 03:11:44

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:11:41', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '9f65b88f-b62c-4472-a062-dc71d7703bde' User entered '21 Sep 2020 22:11'	System	22 Sep 2020 03:11:44
	System	22 Sep 2020 03:11:44

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 5'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:01:08', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f65540c5-9681-4dd3-b27e-351432f3e1a3' User entered 'Yes (Y)'	System	22 Sep 2020 17:03:55
	System	22 Sep 2020 17:03:55

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:01:48', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f65540c5-9681-4dd3-b27e-351432f3e1a3' User entered '95.3'	System	22 Sep 2020 17:03:55
	System	22 Sep 2020 17:03:55

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:01:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f65540c5-9681-4dd3-b27e-351432f3e1a3'	System	22 Sep 2020 17:03:55
User entered 'No (N)'	System	22 Sep 2020 17:03:55

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:01:58', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f65540c5-9681-4dd3-b27e-351432f3e1a3' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:03:55
	System	22 Sep 2020 17:03:55

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 6'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:09:31', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '69719da8-2bd1-4699-a634-5c1fec85d879'	System	23 Sep 2020 18:10:09
User entered 'Yes (Y)'	System	23 Sep 2020 18:10:09

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:09:48', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '69719da8-2bd1-4699-a634-5c1fec85d879' User entered '97.8'	System	23 Sep 2020 18:10:09
	System	23 Sep 2020 18:10:09

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:09:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '69719da8-2bd1-4699-a634-5c1fec85d879' User entered 'No (N)'	System	23 Sep 2020 18:10:09
	System	23 Sep 2020 18:10:09

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:10:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '69719da8-2bd1-4699-a634-5c1fec85d879'	System	23 Sep 2020 18:10:09
User entered '23 Sep 2020 13:10'	System	23 Sep 2020 18:10:09

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 7'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:56:48', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b881e754-c936-4109-a84f-aaef3c6961e0' User entered 'Yes (Y)'	System	24 Sep 2020 23:58:00
	System	24 Sep 2020 23:58:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:57:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b881e754-c936-4109-a84f-aaef3c6961e0' User entered '96.5'	System	24 Sep 2020 23:58:00
	System	24 Sep 2020 23:58:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:57:53', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b881e754-c936-4109-a84f-aaef3c6961e0' User entered 'No (N)'	System	24 Sep 2020 23:58:00
	System	24 Sep 2020 23:58:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:57:57', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b881e754-c936-4109-a84f-aaef3c6961e0' User entered '24 Sep 2020 18:57'	System	24 Sep 2020 23:58:00
	System	24 Sep 2020 23:58:00

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2c6a24f5-8d94-49ae-ab33-a2c9d320bf06'	System	18 Sep 2020 16:23:43
User entered 'None (1)'	System	18 Sep 2020 16:23:43

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:27', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2c6a24f5-8d94-49ae-ab33-a2c9d320bf06'	System	18 Sep 2020 16:23:43
User entered 'No (N)'	System	18 Sep 2020 16:23:43

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:33', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2c6a24f5-8d94-49ae-ab33-a2c9d320bf06'	System	18 Sep 2020 16:23:43
User entered 'No (N)'	System	18 Sep 2020 16:23:43

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2c6a24f5-8d94-49ae-ab33-a2c9d320bf06'	System	18 Sep 2020 16:23:43
User entered 'None (1)'	System	18 Sep 2020 16:23:43

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:41', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2c6a24f5-8d94-49ae-ab33-a2c9d320bf06' User entered '18 Sep 2020 11:23'	System	18 Sep 2020 16:23:43
	System	18 Sep 2020 16:23:43

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 11:03'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 13:33'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:50:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d76ba4-85c9-4e75-a6b1-4184541efefb' User entered 'None (1)'	System	19 Sep 2020 14:50:49
	System	19 Sep 2020 14:50:49

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:50:16', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d76ba4-85c9-4e75-a6b1-4184541efefb' User entered 'No (N)'	System	19 Sep 2020 14:50:49
	System	19 Sep 2020 14:50:49

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:50:21', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d76ba4-85c9-4e75-a6b1-4184541efefb' User entered 'No (N)'	System	19 Sep 2020 14:50:49
	System	19 Sep 2020 14:50:49

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:50:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d76ba4-85c9-4e75-a6b1-4184541efefb' User entered 'None (1)'	System	19 Sep 2020 14:50:49
	System	19 Sep 2020 14:50:49

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:50:47', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d76ba4-85c9-4e75-a6b1-4184541efefb' User entered '19 Sep 2020 09:50'	System	19 Sep 2020 14:50:49
	System	19 Sep 2020 14:50:49

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 14:28'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 2'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1e0f2a6a-9f08-42fd-bbf5-72c2b785e9be'	System	19 Sep 2020 17:04:30
User entered 'None (1)'	System	19 Sep 2020 17:04:30

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1e0f2a6a-9f08-42fd-bbf5-72c2b785e9be' User entered 'No (N)'	System	19 Sep 2020 17:04:30
	System	19 Sep 2020 17:04:30

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:12', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1e0f2a6a-9f08-42fd-bbf5-72c2b785e9be' User entered 'No (N)'	System	19 Sep 2020 17:04:30
	System	19 Sep 2020 17:04:30

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:18', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1e0f2a6a-9f08-42fd-bbf5-72c2b785e9be'	System	19 Sep 2020 17:04:30
User entered 'None (1)'	System	19 Sep 2020 17:04:30

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:28', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1e0f2a6a-9f08-42fd-bbf5-72c2b785e9be' User entered '19 Sep 2020 12:04'	System	19 Sep 2020 17:04:30
	System	19 Sep 2020 17:04:30

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 3'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:24', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e493d98e-0010-409d-8231-38683c434947'	System	21 Sep 2020 14:16:48
User entered 'None (1)'	System	21 Sep 2020 14:16:48

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e493d98e-0010-409d-8231-38683c434947'	System	21 Sep 2020 14:16:48
User entered 'No (N)'	System	21 Sep 2020 14:16:48

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:33', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e493d98e-0010-409d-8231-38683c434947'	System	21 Sep 2020 14:16:48
User entered 'No (N)'	System	21 Sep 2020 14:16:48

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e493d98e-0010-409d-8231-38683c434947'	System	21 Sep 2020 14:16:48
User entered 'None (1)'	System	21 Sep 2020 14:16:48

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:45', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e493d98e-0010-409d-8231-38683c434947'	System	21 Sep 2020 14:16:48
User entered '21 Sep 2020 09:15'	System	21 Sep 2020 14:16:48

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 4'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:11:53', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '950a6f28-6ca2-41a4-b116-75a8628a6151'	System	22 Sep 2020 03:12:39
User entered 'None (1)'	System	22 Sep 2020 03:12:39

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:11:58', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '950a6f28-6ca2-41a4-b116-75a8628a6151' User entered 'No (N)'	System	22 Sep 2020 03:12:39
	System	22 Sep 2020 03:12:39

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:12:11', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '950a6f28-6ca2-41a4-b116-75a8628a6151' User entered 'No (N)'	System	22 Sep 2020 03:12:39
	System	22 Sep 2020 03:12:39

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:12:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '950a6f28-6ca2-41a4-b116-75a8628a6151'	System	22 Sep 2020 03:12:39
User entered 'None (1)'	System	22 Sep 2020 03:12:39

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:12:38', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '950a6f28-6ca2-41a4-b116-75a8628a6151' User entered '21 Sep 2020 22:12'	System	22 Sep 2020 03:12:39
	System	22 Sep 2020 03:12:39

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 5'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0649a686-e9a0-495a-a5fa-86e537d4018b' User entered 'None (1)'	System	22 Sep 2020 17:16:32
	System	22 Sep 2020 17:16:32

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:11', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0649a686-e9a0-495a-a5fa-86e537d4018b' User entered 'No (N)'	System	22 Sep 2020 17:16:32
	System	22 Sep 2020 17:16:32

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:18', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0649a686-e9a0-495a-a5fa-86e537d4018b' User entered 'No (N)'	System	22 Sep 2020 17:16:32
	System	22 Sep 2020 17:16:32

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:23', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0649a686-e9a0-495a-a5fa-86e537d4018b' User entered 'None (1)'	System	22 Sep 2020 17:16:32
	System	22 Sep 2020 17:16:32

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0649a686-e9a0-495a-a5fa-86e537d4018b' User entered '22 Sep 2020 12:16'	System	22 Sep 2020 17:16:32
	System	22 Sep 2020 17:16:32

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 6'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:10:14', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9c18813-dd92-4254-b3c3-0e6b54098101'	System	23 Sep 2020 18:11:11
User entered 'None (1)'	System	23 Sep 2020 18:11:11

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:10:18', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9c18813-dd92-4254-b3c3-0e6b54098101' User entered 'No (N)'	System	23 Sep 2020 18:11:11
	System	23 Sep 2020 18:11:11

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:10:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9c18813-dd92-4254-b3c3-0e6b54098101' User entered 'No (N)'	System	23 Sep 2020 18:11:11
	System	23 Sep 2020 18:11:11

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:03', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9c18813-dd92-4254-b3c3-0e6b54098101' User entered 'None (1)'	System	23 Sep 2020 18:11:11
	System	23 Sep 2020 18:11:11

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:08', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9c18813-dd92-4254-b3c3-0e6b54098101' User entered '23 Sep 2020 13:11'	System	23 Sep 2020 18:11:11
	System	23 Sep 2020 18:11:11

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 7'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:13', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '550119aa-ff91-47ba-864a-b43b48ba25e5' User entered 'None (1)'	System	24 Sep 2020 23:58:40
	System	24 Sep 2020 23:58:40

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '550119aa-ff91-47ba-864a-b43b48ba25e5' User entered 'No (N)'	System	24 Sep 2020 23:58:40
	System	24 Sep 2020 23:58:40

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:27', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '550119aa-ff91-47ba-864a-b43b48ba25e5' User entered 'No (N)'	System	24 Sep 2020 23:58:40
	System	24 Sep 2020 23:58:40

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '550119aa-ff91-47ba-864a-b43b48ba25e5' User entered 'None (1)'	System	24 Sep 2020 23:58:40
	System	24 Sep 2020 23:58:40

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:38', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '550119aa-ff91-47ba-864a-b43b48ba25e5' User entered '24 Sep 2020 18:58'	System	24 Sep 2020 23:58:40
	System	24 Sep 2020 23:58:40

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:47', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99' User entered 'None (0)'	System	18 Sep 2020 16:24:21
	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:56', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99' User entered 'None (0)'	System	18 Sep 2020 16:24:21
	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:23:59', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99' User entered 'None (0)'	System	18 Sep 2020 16:24:21
	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:24:03', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99' User entered 'None (0)'	System	18 Sep 2020 16:24:21
	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:24:06', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99' User entered 'None (0)'	System	18 Sep 2020 16:24:21
	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:24:09', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99' User entered 'None (0)'	System	18 Sep 2020 16:24:21
	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:24:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99'	System	18 Sep 2020 16:24:21
User entered 'No (N)'	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-18T11:24:19', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '80e4a8df-6289-42c0-b3f5-d5effc45ad99' User entered '18 Sep 2020 11:24'	System	18 Sep 2020 16:24:21
	System	18 Sep 2020 16:24:21

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 11:03'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 13:33'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:50:57', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033' User entered 'None (0)'	System	19 Sep 2020 14:51:32
	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:51:03', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033' User entered 'None (0)'	System	19 Sep 2020 14:51:32
	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:51:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033' User entered 'None (0)'	System	19 Sep 2020 14:51:32
	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:51:14', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033' User entered 'None (0)'	System	19 Sep 2020 14:51:32
	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:51:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033' User entered 'None (0)'	System	19 Sep 2020 14:51:32
	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:51:21', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033' User entered 'None (0)'	System	19 Sep 2020 14:51:32
	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:51:27', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033'	System	19 Sep 2020 14:51:32
User entered 'No (N)'	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T09:51:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '1d7a8fdb-fc0c-4053-a9c5-7b93202d3033' User entered '19 Sep 2020 09:51'	System	19 Sep 2020 14:51:32
	System	19 Sep 2020 14:51:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '18 Sep 2020 14:28'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 2'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:36', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06' User entered 'None (0)'	System	19 Sep 2020 17:05:18
	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:40', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06' User entered 'None (0)'	System	19 Sep 2020 17:05:18
	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:50', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06' User entered 'None (0)'	System	19 Sep 2020 17:05:18
	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:04:57', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06' User entered 'None (0)'	System	19 Sep 2020 17:05:18
	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06' User entered 'None (0)'	System	19 Sep 2020 17:05:18
	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:05:06', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06' User entered 'None (0)'	System	19 Sep 2020 17:05:18
	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:05:12', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06'	System	19 Sep 2020 17:05:18
User entered 'No (N)'	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-19T12:05:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dbef8e17-84a3-4057-a8e3-4677b93f5f06'	System	19 Sep 2020 17:05:18
User entered '19 Sep 2020 12:05'	System	19 Sep 2020 17:05:18

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 3'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:51', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered 'None (0)'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered 'None (0)'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:15:58', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered 'None (0)'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:16:02', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered 'None (0)'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:16:06', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered 'None (0)'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:16:09', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered 'None (0)'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:16:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered 'No (N)'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T09:16:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'fd9cad8c-3353-4ee7-8ad9-afe041a3f709' User entered '21 Sep 2020 09:16'	System	21 Sep 2020 14:17:27
	System	21 Sep 2020 14:17:27

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 4'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:04', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered 'None (0)'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:08', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered 'None (0)'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:12', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered 'None (0)'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered 'None (0)'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:21', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered 'None (0)'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered 'None (0)'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered 'No (N)'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-21T22:13:45', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4b4ec6f7-9e79-40b4-83ac-75be62384ae8' User entered '21 Sep 2020 22:13'	System	22 Sep 2020 03:13:52
	System	22 Sep 2020 03:13:52

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 5'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:32', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered 'None (0)'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:35', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered 'None (0)'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:38', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered 'None (0)'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:41', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered 'None (0)'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:46', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered 'None (0)'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:49', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered 'None (0)'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:52', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered 'No (N)'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-22T12:16:56', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3e536663-dbed-4f00-a0b5-19289aa2a652' User entered '22 Sep 2020 12:16'	System	22 Sep 2020 17:17:00
	System	22 Sep 2020 17:17:00

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 6'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered 'None (0)'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:19', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered 'None (0)'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:22', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered 'None (0)'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered 'None (0)'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered 'None (0)'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:32', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered 'None (0)'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered 'No (N)'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-23T13:11:51', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '512467ac-1722-4a90-8cf3-b6009dc129a1' User entered '23 Sep 2020 13:11'	System	23 Sep 2020 18:11:56
	System	23 Sep 2020 18:11:56

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	18 Sep 2020 16:01:19
User entered 'Day 7'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:48', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered 'None (0)'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:52', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered 'None (0)'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:58:57', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered 'None (0)'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:59:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered 'None (0)'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:59:04', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered 'None (0)'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:59:08', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered 'None (0)'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:59:14', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered 'No (N)'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-09-24T18:59:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c09a91b-5664-4109-a455-f27cc2a6c8f6' User entered '24 Sep 2020 18:59'	System	24 Sep 2020 23:59:32
	System	24 Sep 2020 23:59:32

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:01:19

US3812229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:01:19

US3812229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:43:05
User entered 'Yes (Y)'	Karen Knapp (b) (4)	26 Sep 2020 17:13:28
	(b) (4)	

US3812229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 20:43:05
User entered '26 Sep 2020'	Karen Knapp (b) (4)	26 Sep 2020 17:13:28
	(b) (4)	

US3812229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:43:05
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	26 Sep 2020 17:13:28
	(b) (4)	

US3812229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:43:05
User entered empty.	Karen Knapp (b) (4)	26 Sep 2020 17:13:28
	(b) (4)	

US3812229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:43:22
User entered 'Yes (Y)'	Karen Knapp (b) (4)	26 Sep 2020 17:13:32
	(b) (4)	

US3812229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'I'	System	26 Sep 2020 17:13:32

US3812229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:44:12
User entered 'Yes (Y)'	Karen Knapp (b) (4)	02 Oct 2020 19:49:27
	(b) (4)	

US3812229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:44:12
User entered '2 Oct 2020'	Karen Knapp (b) (4)	02 Oct 2020 19:49:27
	(b) (4)	

US3812229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:44:12
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	02 Oct 2020 19:49:27
	(b) (4)	

US3812229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:44:12
User entered empty.	Karen Knapp (b) (4)	02 Oct 2020 19:49:27
	(b) (4)	

US3812229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:44:25
User entered 'Yes (Y)'	Karen Knapp (b) (4)	02 Oct 2020 19:49:32
	(b) (4)	

US3812229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'I'	System	02 Oct 2020 19:49:32

US3812229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:01
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Oct 2020 19:26:46
	(b) (4)	

US3812229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:01
User entered '9 Oct 2020'	Karen Knapp (b) (4)	09 Oct 2020 19:26:46
	(b) (4)	

US3812229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:01
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	09 Oct 2020 19:26:46
	(b) (4)	

US3812229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:01
User entered empty.	Karen Knapp (b) (4)	09 Oct 2020 19:26:46
	(b) (4)	

US3812229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:15
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Oct 2020 19:26:50
	(b) (4)	

US3812229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'I'	System	09 Oct 2020 19:26:50

US3812229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:40
User entered 'Yes (Y)'	Heather Cherniawski	23 Oct 2020 19:04:34
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:40
User entered '14 Oct 2020'	Heather Cherniawski	23 Oct 2020 19:04:34
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:40
User entered 'Clinic (Clinic)'	Heather Cherniawski	23 Oct 2020 19:04:34
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'VISIT3'	System	23 Oct 2020 19:04:34

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered 'Yes (Y)'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered '14 Oct 2020'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered '10:47'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered '14 Oct 2020 10:47'	System	23 Oct 2020 19:05:28

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered '98.0' F	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered 'Oral (Oral)'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered empty.	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered '84'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'bpm'	System	23 Oct 2020 19:05:28

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered '16'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'breaths/min'	System	23 Oct 2020 19:05:28

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (.xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered '132'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'mmHg'	System	23 Oct 2020 19:05:28

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:45:59
User entered '82'	Heather Cherniawski	23 Oct 2020 19:05:28
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'mmHg'	System	23 Oct 2020 19:05:28

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24

US3812229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24

US3812229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:46:21
User entered 'No (N)'	Heather Cherniawski	23 Oct 2020 19:06:09
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:46:21
User entered empty.	Heather Cherniawski	23 Oct 2020 19:06:09
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
	(b) (4)	
	(b) (4), (b) (6)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 14OCT2020, however, per GCL, they have an Unscheduled sample collected on 14OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 23:10:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:46:47
	(b) (4)	
Query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 14OCT2020, however, per GCL, they have an Unscheduled sample collected on 14OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' answered with 'VISIT 3 DAY 57' (Site from DM).	Breanna Galibert (b) (4)	12 Nov 2020 16:54:39
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: There is a Visit 3 Day 57 sample collected on 14OCT2020, however, per GCL, they have an Unscheduled sample collected on 14OCT2020. Please clarify if this sample should be labeled as Visit 3 Day 57 or Unscheduled, and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 14:33:35
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	23 Oct 2020 19:07:03

US3812229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:46:47
User entered '14 Oct 2020'	Heather Cherniawski	23 Oct 2020 19:07:03
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:46:47
User entered '10:55'	Heather Cherniawski	23 Oct 2020 19:07:03
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered '14 Oct 2020 10:55'	System	23 Oct 2020 19:07:03

US3812229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 20:47:04
User entered 'Yes (Y)'	Heather Cherniawski	23 Oct 2020 19:07:09
	(b) (4)	

US3812229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:53:24
User entered 'I'	System	23 Oct 2020 19:07:09

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 64'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-10-22T22:23:06', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3ae62296-331c-457c-a7c8-7b6eaaa2fd77'	System	23 Oct 2020 03:23:38
User entered 'No (N)'	System	23 Oct 2020 03:23:38

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-10-22T22:23:21', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3ae62296-331c-457c-a7c8-7b6eaaa2fd77'	System	23 Oct 2020 03:23:38
User entered 'No (N)'	System	23 Oct 2020 03:23:38

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-10-22T22:23:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '3ae62296-331c-457c-a7c8-7b6eaaa2fd77' User entered '22 Oct 2020 22:23:37'	System	23 Oct 2020 03:23:38
	System	23 Oct 2020 03:23:38

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 71'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-10-28T05:59:13', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '20599ed6-daa0-4f05-93c4-46ad6dab87a0' User entered 'No (N)'	System	28 Oct 2020 11:00:03
	System	28 Oct 2020 11:00:03

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-10-28T05:59:23', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '20599ed6-daa0-4f05-93c4-46ad6dab87a0'	System	28 Oct 2020 11:00:03
User entered 'No (N)'	System	28 Oct 2020 11:00:03

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-10-28T05:59:59', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '20599ed6-daa0-4f05-93c4-46ad6dab87a0' User entered '28 Oct 2020 05:59:59'	System	28 Oct 2020 11:00:03
	System	28 Oct 2020 11:00:03

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 78'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-04T11:44:06', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2b8f0ab5-a236-4814-9474-e44fa4e571ce' User entered 'No (N)'	System	04 Nov 2020 17:44:54
	System	04 Nov 2020 17:44:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-04T11:44:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2b8f0ab5-a236-4814-9474-e44fa4e571ce' User entered 'No (N)'	System	04 Nov 2020 17:44:54
	System	04 Nov 2020 17:44:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-04T11:44:50', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2b8f0ab5-a236-4814-9474-e44fa4e571ce' User entered '04 Nov 2020 11:44:50'	System	04 Nov 2020 17:44:54
	System	04 Nov 2020 17:44:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered 'Day 92'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:16:23', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:16:31', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered 'No (N)'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Per Investigator note, subject reported previous week symptoms which had resolved. subject was also in an illness visit' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 16:11:02
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Anya Penly (b) (4) (b) (4)	23 Dec 2020 16:21:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:16:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5' User entered '1'	System	18 Nov 2020 14:17:54
	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '1'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '1'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '1'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '1'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:01', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered '0'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Please 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)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:15', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:26', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered 'Yes (Y)'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Please 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)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5'	System	18 Nov 2020 14:17:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-18T08:17:44', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0b09f61-40b7-4225-8728-13963e1bdc5' User entered '18 Nov 2020 08:17:44'	System	18 Nov 2020 14:17:54
	System	18 Nov 2020 14:17:54

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 15:14:11

US3812229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:53:01
Data entry locked.	System	21 Aug 2020 15:14:11
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 15:14:11

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-22T11:23:08', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2811d9f8-c529-4e90-b056-975c21423c77'	System	22 Nov 2020 17:23:40
User entered 'No (N)'	System	22 Nov 2020 17:23:40

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-22T11:23:34', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2811d9f8-c529-4e90-b056-975c21423c77'	System	22 Nov 2020 17:23:40
User entered 'No (N)'	System	22 Nov 2020 17:23:40

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-22T11:23:39', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '2811d9f8-c529-4e90-b056-975c21423c77'	System	22 Nov 2020 17:23:40
User entered '22 Nov 2020 11:23:39'	System	22 Nov 2020 17:23:40

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-29T10:25:19', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e2195ad-1a44-4094-8c8e-49986faf0fb7' User entered 'No (N)'	System	29 Nov 2020 16:25:58
	System	29 Nov 2020 16:25:58

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-29T10:25:38', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e2195ad-1a44-4094-8c8e-49986faf0fb7'	System	29 Nov 2020 16:25:58
User entered 'No (N)'	System	29 Nov 2020 16:25:58

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-11-29T10:25:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7e2195ad-1a44-4094-8c8e-49986faf0fb7' User entered '29 Nov 2020 10:25:54'	System	29 Nov 2020 16:25:58
	System	29 Nov 2020 16:25:58

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-06T09:40:32', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e822432f-eac1-4739-8cce-13fa8df13c8d' User entered 'No (N)'	System	06 Dec 2020 15:41:09
	System	06 Dec 2020 15:41:09

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-06T09:40:46', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e822432f-eac1-4739-8cce-13fa8df13c8d' User entered 'No (N)'	System	06 Dec 2020 15:41:09
	System	06 Dec 2020 15:41:09

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-06T09:41:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'e822432f-eac1-4739-8cce-13fa8df13c8d' User entered '06 Dec 2020 09:41:07'	System	06 Dec 2020 15:41:09
	System	06 Dec 2020 15:41:09

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-13T10:14:57', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '67907cd8-5e3b-4368-83e1-880edf12ddea' User entered 'No (N)'	System	13 Dec 2020 16:15:33
	System	13 Dec 2020 16:15:33

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-13T10:15:07', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '67907cd8-5e3b-4368-83e1-880edf12ddea' User entered 'No (N)'	System	13 Dec 2020 16:15:33
	System	13 Dec 2020 16:15:33

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-13T10:15:30', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '67907cd8-5e3b-4368-83e1-880edf12ddea' User entered '13 Dec 2020 10:15:30'	System	13 Dec 2020 16:15:33
	System	13 Dec 2020 16:15:33

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-20T11:42:31', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9a9a001-e69e-4236-ab23-3aae7a21c67c' User entered 'No (N)'	System	20 Dec 2020 17:42:49
	System	20 Dec 2020 17:42:49

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-20T11:42:40', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9a9a001-e69e-4236-ab23-3aae7a21c67c'	System	20 Dec 2020 17:42:49
User entered 'No (N)'	System	20 Dec 2020 17:42:49

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-20T11:42:47', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f9a9a001-e69e-4236-ab23-3aae7a21c67c' User entered '20 Dec 2020 11:42:47'	System	20 Dec 2020 17:42:49
	System	20 Dec 2020 17:42:49

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-27T19:22:42', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ac22225b-b5cb-40f7-9967-0f86ac6729ad' User entered 'Yes (Y)'	System	28 Dec 2020 01:25:01
	System	28 Dec 2020 01:25:01

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-27T19:24:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ac22225b-b5cb-40f7-9967-0f86ac6729ad' User entered 'No (N)'	System	28 Dec 2020 01:25:01
	System	28 Dec 2020 01:25:01

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-27T19:24:28', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ac22225b-b5cb-40f7-9967-0f86ac6729ad' User entered 'No (N)'	System	28 Dec 2020 01:25:01
	System	28 Dec 2020 01:25:01

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-27T19:24:36', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ac22225b-b5cb-40f7-9967-0f86ac6729ad' User entered 'No (N)'	System	28 Dec 2020 01:25:01
	System	28 Dec 2020 01:25:01

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2020-12-27T19:24:59', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ac22225b-b5cb-40f7-9967-0f86ac6729ad' User entered '27 Dec 2020 19:24:59'	System	28 Dec 2020 01:25:01
	System	28 Dec 2020 01:25:01

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-03T11:55:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '82ed2d6c-a71e-495c-83f0-f4f03ad5ae82' User entered 'No (N)'	System	03 Jan 2021 17:55:49
	System	03 Jan 2021 17:55:49

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-03T11:55:11', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '82ed2d6c-a71e-495c-83f0-f4f03ad5ae82'	System	03 Jan 2021 17:55:49
User entered 'No (N)'	System	03 Jan 2021 17:55:49

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-03T11:55:48', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '82ed2d6c-a71e-495c-83f0-f4f03ad5ae82' User entered '03 Jan 2021 11:55:48'	System	03 Jan 2021 17:55:49
	System	03 Jan 2021 17:55:49

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-10T10:13:24', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '910163cc-819e-40f1-893a-d8c8d1a84a64'	System	10 Jan 2021 16:14:20
User entered 'Yes (Y)'	System	10 Jan 2021 16:14:20

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-10T10:13:33', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '910163cc-819e-40f1-893a-d8c8d1a84a64' User entered 'No (N)'	System	10 Jan 2021 16:14:20
	System	10 Jan 2021 16:14:20

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-10T10:13:54', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '910163cc-819e-40f1-893a-d8c8d1a84a64' User entered 'No (N)'	System	10 Jan 2021 16:14:20
	System	10 Jan 2021 16:14:20

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-10T10:14:03', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '910163cc-819e-40f1-893a-d8c8d1a84a64' User entered 'No (N)'	System	10 Jan 2021 16:14:20
	System	10 Jan 2021 16:14:20

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-10T10:14:17', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '910163cc-819e-40f1-893a-d8c8d1a84a64' User entered '10 Jan 2021 10:14:17'	System	10 Jan 2021 16:14:20
	System	10 Jan 2021 16:14:20

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-18T10:21:50', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ca1c3b81-263e-486c-8e16-2d99208949e8' User entered 'No (N)'	System	18 Jan 2021 16:22:13
	System	18 Jan 2021 16:22:13

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-18T10:21:59', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ca1c3b81-263e-486c-8e16-2d99208949e8' User entered 'No (N)'	System	18 Jan 2021 16:22:13
	System	18 Jan 2021 16:22:13

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-18T10:22:09', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'ca1c3b81-263e-486c-8e16-2d99208949e8' User entered '18 Jan 2021 10:22:09'	System	18 Jan 2021 16:22:13
	System	18 Jan 2021 16:22:13

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-24T12:28:03', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '31fc7481-87d6-450f-9dd1-3fdd9130ad5a' User entered 'No (N)'	System	24 Jan 2021 18:28:48
	System	24 Jan 2021 18:28:48

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-24T12:28:21', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '31fc7481-87d6-450f-9dd1-3fdd9130ad5a' User entered 'No (N)'	System	24 Jan 2021 18:28:48
	System	24 Jan 2021 18:28:48

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-24T12:28:46', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '31fc7481-87d6-450f-9dd1-3fdd9130ad5a' User entered '24 Jan 2021 12:28:46'	System	24 Jan 2021 18:28:48
	System	24 Jan 2021 18:28:48

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-31T16:43:29', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b5be9dad-7ea7-40f2-a1eb-f49bbbedc9cd' User entered 'No (N)'	System	31 Jan 2021 22:43:53
	System	31 Jan 2021 22:43:53

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-31T16:43:37', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b5be9dad-7ea7-40f2-a1eb-f49bbbedc9cd' User entered 'No (N)'	System	31 Jan 2021 22:43:53

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-01-31T16:43:48', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b5be9dad-7ea7-40f2-a1eb-f49bbbedc9cd' User entered '31 Jan 2021 16:43:48'	System	31 Jan 2021 22:43:53
	System	31 Jan 2021 22:43:53

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-07T11:37:32', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8f85c4a6-32ed-4a6d-81a6-8c309c4da0ef' User entered 'No (N)'	System	07 Feb 2021 17:38:25
	System	07 Feb 2021 17:38:25

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-07T11:37:52', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8f85c4a6-32ed-4a6d-81a6-8c309c4da0ef' User entered 'No (N)'	System	07 Feb 2021 17:38:25
	System	07 Feb 2021 17:38:25

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-07T11:38:21', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8f85c4a6-32ed-4a6d-81a6-8c309c4da0ef' User entered '07 Feb 2021 11:38:21'	System	07 Feb 2021 17:38:25
	System	07 Feb 2021 17:38:25

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-14T09:48:11', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0424d5b-191e-4cb5-bfac-e5fa3cd36007' User entered 'No (N)'	System	14 Feb 2021 15:48:28

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-14T09:48:16', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0424d5b-191e-4cb5-bfac-e5fa3cd36007'	System	14 Feb 2021 15:48:28
User entered 'No (N)'	System	14 Feb 2021 15:48:28

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-14T09:48:22', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'a0424d5b-191e-4cb5-bfac-e5fa3cd36007'	System	14 Feb 2021 15:48:28
User entered '14 Feb 2021 09:48:22'	System	14 Feb 2021 15:48:28

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-22T03:06:44', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd08a213c-37ae-49b0-a166-68fb60768b60' User entered 'No (N)'	System	22 Feb 2021 09:06:57
	System	22 Feb 2021 09:06:57

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-22T03:06:47', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd08a213c-37ae-49b0-a166-68fb60768b60' User entered 'No (N)'	System	22 Feb 2021 09:06:57
	System	22 Feb 2021 09:06:57

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-22T03:06:52', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'd08a213c-37ae-49b0-a166-68fb60768b60' User entered '22 Feb 2021 03:06:52'	System	22 Feb 2021 09:06:57
	System	22 Feb 2021 09:06:57

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:35:28-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '924b90af-649e-403f-bd4f-41bcafec6060' User entered 'Yes (Y)'	System	28 Feb 2021 15:37:45
	System	28 Feb 2021 15:37:45

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:35:34-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '924b90af-649e-403f-bd4f-41bcafec6060' User entered 'No (N)'	System	28 Feb 2021 15:37:45
	System	28 Feb 2021 15:37:45

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:35:44-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '924b90af-649e-403f-bd4f-41bcafec6060' User entered 'No (N)'	System	28 Feb 2021 15:37:45
	System	28 Feb 2021 15:37:45

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:35:52-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '924b90af-649e-403f-bd4f-41bcafec6060' User entered 'Yes (Y)'	System	28 Feb 2021 15:37:45
	System	28 Feb 2021 15:37:45

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Please 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:36:20-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '924b90af-649e-403f-bd4f-41bcafec6060'	System	28 Feb 2021 15:37:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 15:37:45

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:37:35-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '924b90af-649e-403f-bd4f-41bcafec6060' User entered '28 Feb 2021 15:37:35'	System	28 Feb 2021 15:37:45
	System	28 Feb 2021 15:37:45

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-08T11:02:55-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6eee065-ad61-4879-9248-7f2506dd4e8f'	System	08 Mar 2021 17:11:48
User entered 'No (N)'	System	08 Mar 2021 17:11:48

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-08T11:03:02-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6eee065-ad61-4879-9248-7f2506dd4e8f'	System	08 Mar 2021 17:11:48
User entered 'No (N)'	System	08 Mar 2021 17:11:48

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-08T11:03:13-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'b6eee065-ad61-4879-9248-7f2506dd4e8f' User entered '08 Mar 2021 11:03:13'	System	08 Mar 2021 17:11:48
	System	08 Mar 2021 17:11:48

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-14T19:50:59-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c5ffbf5-8806-4033-b04c-f24faf354b22'	System	15 Mar 2021 00:51:25
User entered 'No (N)'	System	15 Mar 2021 00:51:25

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-14T19:51:06-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c5ffbf5-8806-4033-b04c-f24faf354b22'	System	15 Mar 2021 00:51:25
User entered 'No (N)'	System	15 Mar 2021 00:51:25

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-14T19:51:23-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '7c5ffbf5-8806-4033-b04c-f24faf354b22'	System	15 Mar 2021 00:51:25
User entered '14 Mar 2021 19:51:23'	System	15 Mar 2021 00:51:25

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-21T11:20:36-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8a773743-f5b5-46a6-8879-07d8b1ea081a' User entered 'No (N)'	System	21 Mar 2021 16:21:08
	System	21 Mar 2021 16:21:08

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-21T11:20:48-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8a773743-f5b5-46a6-8879-07d8b1ea081a' User entered 'No (N)'	System	21 Mar 2021 16:21:08
	System	21 Mar 2021 16:21:08

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-21T11:21:02-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '8a773743-f5b5-46a6-8879-07d8b1ea081a' User entered '21 Mar 2021 11:21:02'	System	21 Mar 2021 16:21:08
	System	21 Mar 2021 16:21:08

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-29T09:34:17-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dd567c2e-5d2c-47bc-b539-dd6a38acf632'	System	29 Mar 2021 14:34:35
User entered 'No (N)'	System	29 Mar 2021 14:34:35

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-29T09:34:22-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dd567c2e-5d2c-47bc-b539-dd6a38acf632'	System	29 Mar 2021 14:34:35
User entered 'No (N)'	System	29 Mar 2021 14:34:35

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-03-29T09:34:30-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'dd567c2e-5d2c-47bc-b539-dd6a38acf632' User entered '29 Mar 2021 09:34:30'	System	29 Mar 2021 14:34:35
	System	29 Mar 2021 14:34:35

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-04T11:33:20-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4576d090-c92a-4004-8cde-a8297669bd8b' User entered 'No (N)'	System	04 Apr 2021 16:33:41
	System	04 Apr 2021 16:33:41

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-04T11:33:27-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4576d090-c92a-4004-8cde-a8297669bd8b'	System	04 Apr 2021 16:33:41
User entered 'No (N)'	System	04 Apr 2021 16:33:41

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-04T11:33:38-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '4576d090-c92a-4004-8cde-a8297669bd8b' User entered '04 Apr 2021 11:33:38'	System	04 Apr 2021 16:33:41
	System	04 Apr 2021 16:33:41

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-11T10:39:28-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0a24231f-b07e-4369-98d5-64cc0c38fbc7' User entered 'No (N)'	System	11 Apr 2021 15:39:43
	System	11 Apr 2021 15:39:43

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-11T10:39:33-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0a24231f-b07e-4369-98d5-64cc0c38fbc7'	System	11 Apr 2021 15:39:43
User entered 'No (N)'	System	11 Apr 2021 15:39:43

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-11T10:39:41-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '0a24231f-b07e-4369-98d5-64cc0c38fbc7' User entered '11 Apr 2021 10:39:41'	System	11 Apr 2021 15:39:43
	System	11 Apr 2021 15:39:43

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-18T08:38:14-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '072db322-1bd3-4482-8e9b-4b74d358cd7f'	System	18 Apr 2021 13:38:23
User entered 'No (N)'	System	18 Apr 2021 13:38:23

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-18T08:38:16-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '072db322-1bd3-4482-8e9b-4b74d358cd7f'	System	18 Apr 2021 13:38:23
User entered 'No (N)'	System	18 Apr 2021 13:38:23

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-18T08:38:21-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '072db322-1bd3-4482-8e9b-4b74d358cd7f'	System	18 Apr 2021 13:38:23
User entered '18 Apr 2021 08:38:21'	System	18 Apr 2021 13:38:23

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-25T10:37:02-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f22f3a78-11aa-4f71-b303-c435588ea697'	System	25 Apr 2021 15:37:12
User entered 'No (N)'	System	25 Apr 2021 15:37:12

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-25T10:37:05-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f22f3a78-11aa-4f71-b303-c435588ea697'	System	25 Apr 2021 15:37:12
User entered 'No (N)'	System	25 Apr 2021 15:37:12

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-04-25T10:37:10-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: 'f22f3a78-11aa-4f71-b303-c435588ea697'	System	25 Apr 2021 15:37:12
User entered '25 Apr 2021 10:37:10'	System	25 Apr 2021 15:37:12

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-05-02T18:35:40-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '79495d72-ad15-412f-9b88-6935c5540118'	System	02 May 2021 23:35:50
User entered 'No (N)'	System	02 May 2021 23:35:50

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

Have you been exposed to someone with 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 (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-05-02T18:35:43-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '79495d72-ad15-412f-9b88-6935c5540118'	System	02 May 2021 23:35:50
User entered 'No (N)'	System	02 May 2021 23:35:50

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-05-02T18:35:47-05:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '79495d72-ad15-412f-9b88-6935c5540118'	System	02 May 2021 23:35:50
User entered '02 May 2021 18:35:47'	System	02 May 2021 23:35:50

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:28:55

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:28:55

US3812229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:55
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:28:55

US3812229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:52:44

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 17:38:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:37:55-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d1aa04-166c-4672-af20-e794d95d90b4'	System	28 Feb 2021 15:38:22
User entered 'Yes (Y)'	System	28 Feb 2021 15:38:22

US3812229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:52:44

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:38:07-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d1aa04-166c-4672-af20-e794d95d90b4'	System	28 Feb 2021 15:38:22
User entered 'Yes (Y)'	System	28 Feb 2021 15:38:22

US3812229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:52:44

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (24273ECA-73FD-405E-86DD-B78C1AEEAA98)', Time: '2021-02-28T09:38:13-06:00', User OID: 'PatientReportedOutcome (US3812229)', ODM File OID: '54d1aa04-166c-4672-af20-e794d95d90b4' User entered '28 Feb 2021 15:38:13'	System	28 Feb 2021 15:38:22
	System	28 Feb 2021 15:38:22

US3812229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:51
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Nov 2020 19:11:57

US3812229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:51
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '13 Nov 2020'	Karen Knapp (b) (4)	13 Nov 2020 19:11:57

US3812229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:51
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	13 Nov 2020 19:11:57

US3812229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:51
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Karen Knapp (b) (4)	13 Nov 2020 19:11:57

US3812229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:51
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:08
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Nov 2020 19:12:01

US3812229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:51
User entered 'I'	System	13 Nov 2020 19:12:01

US3812229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Dec 2020 20:36:50

US3812229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '17 Dec 2020'	Karen Knapp (b) (4)	17 Dec 2020 20:36:50

US3812229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	17 Dec 2020 20:36:50

US3812229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Karen Knapp (b) (4)	17 Dec 2020 20:36:50

US3812229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:21:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Dec 2020 20:36:55

US3812229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
User entered 'I'	System	17 Dec 2020 20:36:55

US3812229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:36:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	16 Jan 2021 15:49:02

US3812229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:36:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '16 Jan 2021'	Karen Knapp (b) (4)	16 Jan 2021 15:49:02

US3812229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:36:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	16 Jan 2021 15:49:02

US3812229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:36:55
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Karen Knapp (b) (4)	16 Jan 2021 15:49:02

US3812229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:37:10
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	16 Jan 2021 15:49:05

US3812229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
User entered 'I'	System	16 Jan 2021 15:49:05

US3812229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:45:39
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	14 Feb 2021 20:29:13

US3812229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:45:39
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered '14 Feb 2021'	Karen Knapp (b) (4)	14 Feb 2021 20:29:13

US3812229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:45:39
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	14 Feb 2021 20:29:13

US3812229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:45:39
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered empty.	Karen Knapp (b) (4)	14 Feb 2021 20:29:13

US3812229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:45:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
User entered 'Yes (Y)'	Karen Knapp (b) (4)	14 Feb 2021 20:29:17

US3812229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:08:18
User entered 'I'	System	14 Feb 2021 20:29:17

US3812229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:07:57
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:38

US3812229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:07:57
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:38
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[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 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:07:57
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:38

US3812229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered 'VISIT4'	System	08 Mar 2021 18:32:38

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered '10:00'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered '08 Mar 2021 10:00'	System	02 Apr 2021 20:06:28

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered '98.0' F	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered '68'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered 'bpm'	System	02 Apr 2021 20:06:28

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered '16'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered 'breaths/min'	System	02 Apr 2021 20:06:28

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered '116'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered 'mmHg'	System	02 Apr 2021 20:06:28

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:43:44
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:40:47
	(b) (4)	
User entered '74'	Breanna Galibert (b) (4)	02 Apr 2021 20:06:28
	(b) (4)	

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered 'mmHg'	System	02 Apr 2021 20:06:28

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12

US3812229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12

US3812229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:08:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:43

US3812229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:08:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:43

US3812229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:14
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:48

US3812229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:14
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:48

US3812229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:14
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered '10:25'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:48

US3812229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered '08 Mar 2021 10:25'	System	08 Mar 2021 18:32:48

US3812229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:09:19
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:32:53

US3812229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:11:12
User entered 'I'	System	08 Mar 2021 18:32:53

US3812229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:06:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 13:32:42

US3812229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:06:08
User entered '13 Apr 2021'	(b) (4), (b) (6)	14 Apr 2021 13:32:42

US3812229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:06:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Apr 2021 13:32:42

US3812229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:06:08
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 13:32:42

US3812229

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	14 Apr 2021 20:06:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 13:32:48

US3812229

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 13:32:48

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:08:54

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '11:09'	(b) (4) Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:08:54

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:24
User entered '10 Nov 2020 11:09'	System	10 Nov 2020 20:08:54

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4)	10 Nov 2020 20:08:54

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:24
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:48:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Nov 2020 20:08:54

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '08 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:01
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32
	(b) (4)	

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User entered '%'	System	15 Jan 2021 19:44:01
User entered empty.	System	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:01
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32
	(b) (4)	

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:09:32

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '09 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:01
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03
	(b) (4)	

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User entered '%'	System	15 Jan 2021 19:44:01
User entered empty.	System	10 Nov 2020 20:10:03

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:01
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03
	(b) (4)	

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:03

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '97'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User entered '%'	System	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '97.7' F	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:33

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '11 Nov 2020'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '97'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User entered '%'	System	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '97.6' F	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Breanna Galibert (b) (4)	12 Nov 2020 16:49:57

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 5 (Day 5)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '12 Nov 2020'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '99'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
User entered '%'	System	13 Nov 2020 17:10:10

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '97.7' F	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Moderate (Moderate)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

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Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Mild (Mild)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:52:22
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'None (None)'	Heather Cherniawski (b) (4)	13 Nov 2020 17:10:10

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[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)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:50:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:41
User entered '0'	System	10 Nov 2020 20:10:49

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:51:13
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:14:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	30 Oct 2020 23:35:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Saliva Collection form of the illness visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:53:02
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:59:44

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:51:13
User entered '12:47'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:59:44

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:54
User entered '26 Aug 2020 12:47'	System	06 Sep 2020 19:59:44

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:51:13
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:59:44

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:34:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:51:13
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:59:44

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 6 (Day 6)' reason for change:	(b) (4)	
Data Entry Error	Breanna Galibert (b) (4)	28 Oct 2020 23:19:15
User entered 'Day 1 (Day 1)'	(b) (4)	
	Karen Knapp (b) (4)	06 Sep 2020 20:01:00
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '98'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '97.3' F	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:58:01
User closed query 'Per source cough is moderate. Please verify and update if needed. ' (Site from CRA).		17 Nov 2020 19:57:58
Query 'Per source cough is moderate. Please verify and update if needed. ' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4) (b) (4)	12 Nov 2020 16:53:51
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	12 Nov 2020 16:53:38
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:41
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User opened query 'Per source cough is moderate. Please verify and update if needed. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:52:14
User entered 'Mild (Mild)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:19:28
User entered 'Moderate (Moderate)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:00

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:00

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 7 (Day 7)' reason for change:	(b) (4)	
Data Entry Error	Breanna Galibert (b) (4)	28 Oct 2020 23:19:15
User entered 'Day 2 (Day 2)'	(b) (4)	
	Karen Knapp (b) (4)	06 Sep 2020 20:01:52
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '27 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '98'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '98' F	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 22:23:08
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:52

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Mild (Mild)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (2)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:01:52

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 8 (Day 8)' reason for change:	(b) (4)	
Data Entry Error	Breanna Galibert (b) (4)	28 Oct 2020 23:19:15
User entered 'Day 3 (Day 3)'	(b) (4)	
	Karen Knapp (b) (4)	06 Sep 2020 20:03:01
	(b) (4)	

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '28 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '96'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '97.6' F	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (3)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (3)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Mild (Mild)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:01

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (3)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (3)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:01

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	Breanna Galibert (b) (4)	28 Oct 2020 23:19:15
User entered 'Day 4 (Day 4)'	(b) (4)	
	Karen Knapp (b) (4)	06 Sep 2020 20:03:36
	(b) (4)	

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Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '29 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '94'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '97.1' F	Karen Knapp (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:24:09
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:23:20
DataPoint Verified.		05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:03:36

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '21 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	15 Jan 2021 19:44:42
User entered empty.	System	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:17

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User closed query 'Please clarify dates for symptom pages 22-25Aug2020, as they are currently listed as October. ' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 15:24:02
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:24:00
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:59
	(b) (4)	
Query 'Please clarify dates for symptom pages 22-25Aug2020, as they are currently listed as October. ' answered with 'updated' (Site from CRA).	Breanna Galibert (b) (4)	28 Apr 2021 16:14:46
Signature has been broken.	(b) (4)	
	Breanna Galibert (b) (4)	28 Apr 2021 16:13:53
User entered '22 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Breanna Galibert (b) (4)	28 Apr 2021 16:13:53
User opened query 'Please clarify dates for symptom pages 22-25Aug2020, as they are currently listed as October. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 17:38:19
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 17:37:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '22 Oct 2020'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	15 Jan 2021 19:44:42
User entered empty.	System	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:16:39

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:24:09
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:59
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	28 Apr 2021 16:13:53
	(b) (4)	
User entered '23 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	28 Apr 2021 16:13:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '23 Oct 2020'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:48
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	15 Jan 2021 19:44:42
User entered empty.	System	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:02

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Mild (Mild)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

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Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:02

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:24:09
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:16:59
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	28 Apr 2021 16:13:53
User entered '24 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	28 Apr 2021 16:13:53
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:28
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '24 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	15 Jan 2021 19:44:42
User entered empty.	System	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:36:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:17:44

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:24:09
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 22:16:59
	(b) (4)	
Signature has been broken.	Breanna Galibert (b) (4)	28 Apr 2021 16:13:53
	(b) (4)	
User entered '25 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	28 Apr 2021 16:13:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 17:38:32
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '25 Oct 2020'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered '0'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:37:05
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User entered '%'	System	15 Jan 2021 19:44:42
User entered empty.	System	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:37:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Un-verified.	(b) (4)	
	Breanna Galibert (b) (4)	15 Jan 2021 19:44:42
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	15 Jan 2021 19:44:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13
	(b) (4)	

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:18:13

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

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Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:18:13

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:44

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:22:36
User entered 'None (None)'	Breanna Galibert (b) (4)	28 Oct 2020 23:18:13

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per GCL Lab Recon: SARS-CoV-2 : Re-query : SARS-CoV-2 sample with dated of 29AUG2020 in PPD central lab however, SARS-CoV-2 sample dated 26AUG2020 in EDC. Please confirm the correct date of sample collection and update accordingly under appropriate visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 08:20:35
Query 'Per GCL Lab Recon: SARS-CoV-2 : Re-query : SARS-CoV-2 sample with dated of 29AUG2020 in PPD central lab however, SARS-CoV-2 sample dated 26AUG2020 in EDC. Please confirm the correct date of sample collection and update accordingly under appropriate visit.' answered with 'PLEASE NOTE, REPORT DATE IS 29 AUG 2020, HOWEVER COLLECTION DATE OF 26 IN EDC AND GCL PORTAL IS CORRECT' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Nov 2020 23:08:21
User opened query 'Per GCL Lab Recon: SARS-CoV-2 : Re-query : SARS-CoV-2 sample with dated of 29AUG2020 in PPD central lab however, SARS-CoV-2 sample dated 26AUG2020 in EDC. Please confirm the correct date of sample collection and update accordingly under appropriate visit.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:55:00
User closed query 'Per GCL Lab Recon: GCL has a SARS-CoV-2 sample with date of 29AUG2020 however there is no Illness Visit completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:55:00
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:03:14
User closed query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Day 5 with dates of 26AUG2020 and 28AUG2020 respectively however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 04:52:15

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Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Date of Visit](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Day 5 with dates of 26AUG2020 and 28AUG2020 respectively however there is no Saliva Log completed. Please reconcile or clarify ' answered with 'DATA IS CORRECT. PPD NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	29 Oct 2020 22:09:28
Query 'Per GCL Lab Recon: GCL has a SARS-CoV-2 sample with date of 29AUG2020 however there is no Illness Visit completed. Please reconcile or clarify' answered with 'UPDATED' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:15:16
User opened query 'Per GCL Lab Recon: GCL has Saliva Day 3 and Day 5 with dates of 26AUG2020 and 28AUG2020 respectively however there is no Saliva Log completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:18:55
User opened query 'Per GCL Lab Recon: GCL has a SARS-CoV-2 sample with date of 29AUG2020 however there is no Illness Visit completed. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 20:18:16
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:00:11

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Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered '26 Aug 2020'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[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)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 22:03:14
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:44

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:07
User entered '0'	System	06 Sep 2020 20:00:11

US3812229

Folder: Covid-19 Assessment 26 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:52:44

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 23:35:12
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:19:19
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 22:16:59
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	28 Apr 2021 17:15:24
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	28 Apr 2021 17:15:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	28 Apr 2021 17:15:24
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:03:30
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	18 Oct 2020 13:05:11

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User accepted default value 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:54:28
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per GCL Reconciliation: Saliva sample collected on 28AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:30:19
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:54:30
Query 'Per GCL Reconciliation: Saliva sample collected on 28AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' answered with 'CORRECT SALIVA DATE COLLECTED 28 AUG 2020' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	04 Nov 2020 15:02:04
User opened query 'Per GCL Reconciliation: Saliva sample collected on 28AUG2020 is labelled under "Visit 01 Baseline Month 0" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:49:19
User entered '28 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User accepted default value 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:44

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:58:46
User closed query 'Per Saliva Collection Log sample was collected 30Aug2020. Please verify if sample was collected and shipped to lab. ' (Site from CRA). Query 'Per Saliva Collection Log sample was collected 30Aug2020. Please verify if sample was collected and shipped to lab. ' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 19:58:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	12 Nov 2020 16:52:56
User opened query 'Per Saliva Collection Log sample was collected 30Aug2020. Please verify if sample was collected and shipped to lab. ' (Site from CRA). DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4), (b) (6)	12 Nov 2020 16:52:50
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 22:01:38
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	05 Nov 2020 21:59:11
	(b) (4), (b) (6)	05 Nov 2020 21:58:29
	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 19:58:44
User entered '30 Aug 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	12 Nov 2020 16:52:50
DataPoint Un-verified.	(b) (4)	05 Nov 2020 21:59:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:58:32
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:14:01
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User accepted default value 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User accepted default value 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User accepted default value 'Day 14 (Day 14)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User accepted default value 'Day 21 (Day 21)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User accepted default value 'Day 28 (Day 28)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

US3812229

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:38
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:58:34
User entered empty.	Breanna Galibert (b) (4)	28 Oct 2020 23:14:01

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Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

US3812229

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '12 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

US3812229

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

US3812229

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:44

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User closed query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:26:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
Query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	17 Feb 2021 19:26:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 19:26:04
User opened query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:31
User closed query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:31
Query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' answered with 'specimen not collected, covid-19 negative' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:18:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:17:42
User opened query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 11:58:57

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EAB) (1725)

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Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	13 Nov 2020 21:14:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

US3812229

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:15:19
User entered '13 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:15:19
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:14:48
User entered '14 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

US3812229

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:44

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User closed query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:26:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
Query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	17 Feb 2021 19:26:29
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 19:26:04
User opened query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:37
User closed query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:37
Query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' answered with 'specimen not collected, covid-19 negative' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:18:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:18:14
User opened query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 11:59:03

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EAB) (1725)

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Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	13 Nov 2020 21:14:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

US3812229

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:15:19
User entered '13 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:15:19
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:14:48
User entered '16 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:44

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User closed query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:27:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
Query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	17 Feb 2021 19:26:38
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User opened query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:42
User closed query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:42
Query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' answered with 'specimen not collected, covid-19 negative' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:18:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:18:38
User opened query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 11:59:10

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EAB) (1725)

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Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	13 Nov 2020 21:14:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:15:19
User entered '13 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:15:19
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:14:48
User entered '18 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:44

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User closed query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:27:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
Query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	17 Feb 2021 19:26:47
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 19:26:04
User opened query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:47
User closed query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:47
Query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' answered with 'specimen not collected, covid-19 negative' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:18:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:18:49
User opened query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 11:59:16

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EAB) (1725)

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Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	13 Nov 2020 21:14:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:15:19
User entered '13 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:15:19
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:14:48
User entered '20 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:44

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User closed query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:27:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
Query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	17 Feb 2021 19:26:56
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User opened query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:52
User closed query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:52
Query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' answered with 'specimen not collected, covid-19 negative' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:19:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:19:02
User opened query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 11:59:23

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EAB) (1725)

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Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	13 Nov 2020 21:14:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:15:19
User entered '13 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:15:19
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:14:48
User entered '22 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:44

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:44

Was Saliva Collected?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User closed query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 07:27:11
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
Query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4)	17 Feb 2021 19:27:07
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 19:26:04
User opened query 'Per GCL Lab Recon : Saliva: Thank you for your update, however response updated is "No", however Date of collection for saliva is recorded. Please leave Date of collection field as Blank if no sample collected. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:58
User closed query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:16:58
Query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' answered with 'specimen not collected, covid-19 negative' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:19:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 14:19:15
User opened query 'Per GCL Lab Recon : Saliva: Response updated is "NA (COVID-19 Negative)", however a Date of collection for saliva is recorded. Please verify if the sample was collected then amend the response to Yes. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 11:59:30

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EAB) (1725)

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Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:44

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Lyly Dang (b) (4) (b) (4)	13 Nov 2020 21:14:48
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:10:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	17 Feb 2021 19:26:04
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:15:19
User entered '13 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:15:19
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	13 Nov 2020 21:14:48
User entered '24 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	13 Nov 2020 21:14:48
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:12:17

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:02
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:12:45

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:02
User entered '26 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:12:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:02
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:12:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:49
User entered 'SICKD1'	System	28 Oct 2020 23:12:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '26 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '12:58'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User entered '26 Aug 2020 12:58'	System	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '65.0' in	Breanna Galibert (b) (4)	28 Oct 2020 23:13:28
DataPoint set to visible.	(b) (4) System	28 Oct 2020 23:12:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '190.4' lb	Breanna Galibert (b) (4)	28 Oct 2020 23:13:28
DataPoint set to visible.	(b) (4) System	28 Oct 2020 23:12:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '97.3' F	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '67'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User entered 'bpm'	System	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '16'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User entered 'breaths/min'	System	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '140'	Breanna Galibert (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User entered 'mmHg'	System	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:35
User entered '82'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57
User entered 'mmHg'	System	28 Oct 2020 23:13:28

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:28:57

US3812229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:53:25
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:36

US3812229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:53:25
User entered '26 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:36

US3812229

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:52:44

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:41

US3812229

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:29:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 21:50:40
User entered '26 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:13:41

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:13:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:20

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:13:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:20

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:13:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:20

US3812229

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	10 Nov 2020 20:11:20

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '11:20'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 11:20'	System	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Height (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '65.0' in	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45
DataPoint set to visible.	System	10 Nov 2020 20:11:20

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Weight (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '190.0' lb	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45
DataPoint set to visible.	System	10 Nov 2020 20:11:20

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '97.7' F	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '67'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '14'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '140'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:14:35
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '86'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:11:45

US3812229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:15:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:51

US3812229

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:15:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:51

US3812229

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:52:44

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:58

US3812229

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:52:44

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 18:15:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:11:58

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:30:52
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:15:42
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:30:52
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:15:42
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:30:52
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Clinic (Clinic)'	Heather Cherniawski	14 Jan 2021 19:15:42
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 19:15:42

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:16:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 16:44:32
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:14:31

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:16:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4)	09 Mar 2021 16:44:32
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:14:31

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:16:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Placebo (Placebo)'	Heather Cherniawski	14 Jan 2021 19:16:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:31:14
User entered 'Placebo (Placebo)'	Heather Cherniawski	14 Jan 2021 19:16:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 12:31:14
User entered 'Placebo (Placebo)'	Heather Cherniawski	14 Jan 2021 19:16:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:31:04
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:16:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'I'	System	14 Jan 2021 19:16:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:52:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'I'	System	14 Jan 2021 19:16:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '65' in	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '193.6' lb	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '32.28409'	System	14 Jan 2021 19:19:38
DataPoint set to visible.	System	14 Jan 2021 19:16:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '65' in	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '193.6' lb	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '32.28409'	System	14 Jan 2021 19:19:38
DataPoint set to visible.	System	14 Jan 2021 19:16:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '09:08'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '14 Jan 2021 09:08'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '98.0' F	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Oral (Oral)'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '81'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'bpm'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '16'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'breaths/min'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '128'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '74'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '65' in	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '193.6' lb	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '32.28409'	System	14 Jan 2021 19:19:38
DataPoint set to visible.	System	14 Jan 2021 19:16:38

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '10:24'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '14 Jan 2021 10:24'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '97.1' F	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Oral (Oral)'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4)	
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '70'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'bpm'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'breaths/min'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '128'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:43
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '84'	Heather Cherniawski	14 Jan 2021 19:19:38
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	14 Jan 2021 19:19:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:52
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:18:15
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:33:52
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:18:15
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:18:06
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Heather Cherniawski	14 Jan 2021 19:18:06
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

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)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Heather Cherniawski	14 Jan 2021 19:18:06
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mRNA-1273'	System	14 Jan 2021 19:18:06
DataPoint set to visible.	System	14 Jan 2021 19:16:38

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:18:06
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:34:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '09:53'	Heather Cherniawski	14 Jan 2021 19:18:06
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '14 Jan 2021 09:53'	System	14 Jan 2021 19:18:06

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:34:42
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	14 Jan 2021 19:18:06
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:34:42
User entered 'ONCE'	System	14 Jan 2021 19:18:06

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 19:18:06

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:35:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:17:30
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:35:18
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:17:30
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4)	
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:35:18
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '09:45'	Heather Cherniawski	14 Jan 2021 19:17:30
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '14 Jan 2021 09:45'	System	14 Jan 2021 19:17:30

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:35:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:17:41
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:35:25
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14 Jan 2021'	Heather Cherniawski	14 Jan 2021 19:17:41
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:35:25
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '09:50'	Heather Cherniawski	14 Jan 2021 19:17:41
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:52:44

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '14 Jan 2021 09:50'	System	14 Jan 2021 19:17:41

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:35:30
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	14 Jan 2021 19:19:51
	(b) (4)	

US3812229

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'I'	System	14 Jan 2021 19:19:51

US3812229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:37:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Jan 2021 20:26:53
	(b) (4)	

US3812229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:37:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '21 Jan 2021'	Karen Knapp (b) (4)	21 Jan 2021 20:26:53
	(b) (4)	

US3812229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:37:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	21 Jan 2021 20:26:53
	(b) (4)	

US3812229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:37:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	21 Jan 2021 20:26:53
	(b) (4)	

US3812229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
	(b) (4)	
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:37:39
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Jan 2021 20:26:57
	(b) (4)	

US3812229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
User entered 'I'	System	21 Jan 2021 20:26:57

US3812229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
User entered 'I'	System	21 Jan 2021 20:26:57
DataPoint set to visible.	System	21 Jan 2021 20:26:57

US3812229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:39:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 15:22:12
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:39:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 15:22:12
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:39:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Clinic (Clinic)'	Heather Cherniawski	11 Feb 2021 15:22:12
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'OLD29'	System	11 Feb 2021 15:22:12

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User accepted default value 'Pre-Dose (PREDOSE)'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '08:45'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '11 Feb 2021 08:45'	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 08:02:15
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per sub i ' (Site from System).	Breanna Galibert (b) (4)	17 Feb 2021 19:29:08
	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Feb 2021 15:23:34
User entered '96.2' F	Heather Cherniawski (b) (4)	11 Feb 2021 15:23:34

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Oral (Oral)'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '76'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'bpm'	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '14'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'breaths/min'	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '128'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '70'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User accepted default value 'Post-Dose (POSTDOSE)'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '11 Feb 2021'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '09:39'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '11 Feb 2021 09:39'	System	11 Feb 2021 15:23:34

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:43:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Feb 2021 15:43:12
User entered '96.8' F reason for change: New Information	Breanna Galibert (b) (4)	11 Feb 2021 15:43:12
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:23:34
User entered empty.	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Oral (Oral)'	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:43:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Feb 2021 15:43:12
User entered '70' reason for change: New Information	Breanna Galibert (b) (4)	11 Feb 2021 15:43:12
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:23:34
User entered empty.	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'bpm'	System	11 Feb 2021 15:43:12
User entered empty.	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
	(b) (4), (b) (6)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:43:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Feb 2021 15:43:12
User entered '14' reason for change: New Information	Breanna Galibert (b) (4)	11 Feb 2021 15:43:12
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:23:34
User entered empty.	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'breaths/min'	System	11 Feb 2021 15:43:12
User entered empty.	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:43:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Feb 2021 15:43:12
User entered '114' reason for change: New Information	Breanna Galibert (b) (4)	11 Feb 2021 15:43:12
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:23:34
User entered empty.	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	11 Feb 2021 15:43:12
User entered empty.	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:29
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:43:12
Query 'Data is required. Please provide.' answered by System data change (Site from System).		11 Feb 2021 15:43:12
User entered '82' reason for change: New Information	Breanna Galibert (b) (4)	11 Feb 2021 15:43:12
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Feb 2021 15:23:34
User entered empty.	Heather Cherniawski	11 Feb 2021 15:23:34
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	11 Feb 2021 15:43:12
User entered empty.	System	11 Feb 2021 15:23:34

US3812229

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'No (N)'	Heather Cherniawski	11 Feb 2021 15:22:47
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:43:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Heather Cherniawski	11 Feb 2021 15:22:47
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 15:22:30
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
User entered empty.	Heather Cherniawski	11 Feb 2021 15:22:30
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

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)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
User entered empty.	Heather Cherniawski	11 Feb 2021 15:22:30
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mRNA-1273'	System	11 Feb 2021 15:22:30
DataPoint set to visible.	System	21 Jan 2021 20:26:57

US3812229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:00
User closed query 'Per GCL Lab Recon: Immunogenicity Sample was reported under Visit OL-D29 dated 11Feb2021 in PPD Central lab; however Immunogenicity Assessment is missing in EDC. Please reconcile' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 09:30:01
Query 'Per GCL Lab Recon: Immunogenicity Sample was reported under Visit OL-D29 dated 11Feb2021 in PPD Central lab; however Immunogenicity Assessment is missing in EDC. Please reconcile' answered with 'samples collected and shipped in error. not required per protocol. please discard samples and pd will be submitted' (Site from DM).	Angie Kean (b) (4)	26 Mar 2021 17:56:43
User opened query 'Per GCL Lab Recon: Immunogenicity Sample was reported under Visit OL-D29 dated 11Feb2021 in PPD Central lab; however Immunogenicity Assessment is missing in EDC. Please reconcile' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	23 Mar 2021 01:37:05
User entered '11 Feb 2021'	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	Heather Cherniawski (b) (4)	11 Feb 2021 15:22:30

US3812229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:00
	(b) (4), (b) (6)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
User entered '09:09'	Heather Cherniawski	11 Feb 2021 15:22:30
	(b) (4)	

US3812229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '11 Feb 2021 09:09'	System	11 Feb 2021 15:22:30

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	11 Feb 2021 15:22:30
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:00
User entered 'ONCE'	System	11 Feb 2021 15:22:30

US3812229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 15:22:30

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:44:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	11 Feb 2021 15:22:15
	(b) (4)	

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'I'	System	11 Feb 2021 15:22:15

US3812229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:46:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Feb 2021 21:26:14
	(b) (4)	

US3812229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:46:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered '18 Feb 2021'	Karen Knapp (b) (4)	18 Feb 2021 21:26:14
	(b) (4)	

US3812229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:46:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	18 Feb 2021 21:26:14
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:54
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:46:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	18 Feb 2021 21:26:14
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4)	
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:46:23
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:29:13
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Feb 2021 21:26:18
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'I'	System	18 Feb 2021 21:26:18

US3812229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:48:32
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:26
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:48:32
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:26
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:48:32
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:26
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'OLD57'	System	08 Mar 2021 18:33:26

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
	(b) (4), (b) (6)	
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '10:00'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '08 Mar 2021 10:00'	System	08 Mar 2021 18:33:53

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '98.0' F	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '68'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'bpm'	System	08 Mar 2021 18:33:53

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '16'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'breaths/min'	System	08 Mar 2021 18:33:53

US3812229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '116'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	08 Mar 2021 18:33:53

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '74'	Breanna Galibert (b) (4)	08 Mar 2021 18:33:53
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered 'mmHg'	System	08 Mar 2021 18:33:53

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:44

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46

US3812229

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:11
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:34:05
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:11
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:34:05
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:34:14
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '08 Mar 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:34:14
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:49:20
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:54:21
	(b) (4)	
User entered '10:25'	Breanna Galibert (b) (4)	08 Mar 2021 18:34:14
	(b) (4)	

US3812229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:34:46
User entered '08 Mar 2021 10:25'	System	08 Mar 2021 18:34:14

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:52:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:55
User closed query 'Per DM CLR: Per Day 92 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 04:55:06
Query 'Per DM CLR: Per Day 92 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'per source, subject confirmed this was reported for previous symptoms and subject had already been assessed. No AE to report' (Site from DM).	Angie Kean (b) (4) (b) (4)	29 Mar 2021 15:52:28
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:47
User opened query 'Per DM CLR: Per Day 92 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 09:59:20
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)' reason for change: New Information	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:56:50
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 17:08:22

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Ear injuries NEC, PT: Foreign body in ear, LLT: Foreign body in ear - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 16:58:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 16:58:53
Data point term sent to Coder	System	03 Oct 2020 16:40:58
User entered 'foreign body in left ear'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '07 Sep 2020'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
User entered empty.	System	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '07 Sep 2020'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
User entered empty.	System	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:40:42

US3812229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 09:01:31
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'updated EDC per source' (Site from DM).	Anya Penly (b) (4) (b) (4)	12 Nov 2020 22:17:21
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:10:18
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:52:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Breanna Galibert (b) (4) (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:06:14
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
User entered '0'	System	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30
User entered 'I'	System	03 Oct 2020 16:40:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:18:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Lightheadedness - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 17:22:05
Data point term sent to Coder	(b) (4)	
User entered 'lightheadedness'	System	20 Jan 2021 17:21:04
	Angie Kean (b) (4)	20 Jan 2021 17:20:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '14 Jan 2021'	(b) (4)	
	Angie Kean (b) (4)	20 Jan 2021 17:20:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10:15'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
User entered '14 Jan 2021 10:15'	System	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '14 Jan 2021'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '10:20'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
User entered '14 Jan 2021 10:20'	System	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

US3812229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

US3812229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 19:21:12
User closed query 'Please clarify as Source notes "related", thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 19:21:07
Query 'Please clarify as Source notes "related", thank you!' answered with 'UPDATED' (Site from CRA).	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:50:13
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:50:08
User entered 'Related (RELATED)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:50:08
User opened query 'Please clarify as Source notes "related", thank you!' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:13:54
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:13:29
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:20:17

US3812229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'l'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:12:20
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	20 Jan 2021 17:20:17

US3812229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
User entered '0'	System	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39
User entered 'I'	System	20 Jan 2021 17:20:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:17:39

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 18:48:26
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 18:48:23
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 13:55:03
Un-reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 13:54:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 13:54:34
User entered 'USA-US111-2021-mRNA-1273-P301000012'	System	03 Mar 2021 16:49:00
User entered 'New'	(b) (4), (b) (6)	03 Mar 2021 16:49:00

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:18:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 18:18:48
Data point term sent to Coder	System	02 Mar 2021 18:17:43
User entered 'myocardial infarction'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '25 Feb 2021'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered empty.	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:39:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:47
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User closed query 'PV query: Please consider updating the event end date based on the report of hospitalization starting on 25 Feb 2021 and including 3 days in the ICU.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:47:40
Query 'PV query: Please consider updating the event end date based on the report of hospitalization starting on 25 Feb 2021 and including 3 days in the ICU.' answered with 'condition that is reported lasted one day. Data is correct' (Site from Safety).	Angie Kean (b) (4) (b) (4)	26 Mar 2021 17:58:40
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User opened query 'PV query: Please consider updating the event end date based on the report of hospitalization starting on 25 Feb 2021 and including 3 days in the ICU.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 12:36:28
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:52:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	09 Mar 2021 23:21:24
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 Mar 2021 23:21:24
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:30:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Mar 2021 18:40:14
User entered '25 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4)	08 Mar 2021 18:39:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Mar 2021 18:17:47
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	02 Mar 2021 18:17:47
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	02 Mar 2021 18:17:47
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	02 Mar 2021 18:17:19
User entered '25 Feb 2021'	Angie Kean (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered empty.	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'Grade 4 (Grade 4)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '0'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'I'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'I'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '25 Feb 2021'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:47:12
User closed query 'Please clarify as the hospital records note 27Feb21 as the last day present in the hospital. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:44:20
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:47:50
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'SUBJECT EXPERIENCED AN MI, WAS GIVEN PROPER CARE/TREATMENT' (Site from Safety).	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:17:40
Query 'Please clarify as the hospital records note 27Feb21 as the last day present in the hospital. ' answered with 'Updated' (Site from CRA).	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:05:12
User entered '27 Feb 2021' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:04:57
User opened query 'Please clarify as the hospital records note 27Feb21 as the last day present in the hospital. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:17:32
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 15:16:01
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 12:35:34
User entered '28 Feb 2021'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 15:44:32
User closed query 'Please clarify per above query.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:44:31
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
Query 'Please clarify per above query.' answered with 'updated' (Site from CRA).	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:05:56
User entered '2' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:05:50
User opened query 'Please clarify per above query.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:20:07
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 15:18:26
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '3'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '0'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

US3812229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '0'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '0'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:52:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:52:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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None

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered '0'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User closed query 'PV Query: Please confirm if treatment Hepann is supposed to be Heparin.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 18:48:09
Query 'PV Query: Please confirm if treatment Hepann is supposed to be Heparin.' answered with 'confirm, data entry error. updated' (Site from Safety).	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:06:42
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User opened query 'PV Query: Please confirm if treatment Hepann is supposed to be Heparin.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 12:35:57
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 00:49:54
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:36:23
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:32:01
User entered 'I'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:45:09
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 21:10:34
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'redacted recorded submitted' (Site from Safety).	Angie Kean (b) (4) (b) (4)	17 Apr 2021 01:06:51
DataPoint Un-verified.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:19:37
User entered '1' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:19:37
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		16 Mar 2021 17:05:38

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 17:04:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:32:44
User entered '0'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:02:03
User closed query 'Please clarify as Source notes Recovering/ Resolving. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:01:59
Query 'Please clarify as Source notes Recovering/ Resolving. ' answered with 'updated' (Site from CRA).	Angie Kean (b) (4) (b) (4)	23 Apr 2021 16:12:33
User opened query 'Please clarify as Source notes Recovering/ Resolving. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:49:22
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:48:50
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
Query 'V Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' canceled (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:53:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	09 Mar 2021 23:21:24
User opened query 'V Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:31:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:40:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:39:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:49:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 16:48:52
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
User entered empty.	Angie Kean (b) (4) (b) (4)	02 Mar 2021 18:17:19

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Could you confirm if subject's chronic cough that was noted to have resolved in Dec 2020 would be considered medical history (present prior to beginning of study)?' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 14:40:36
User closed query 'PV Query: Could you confirm if subject's chronic cough that was noted to have resolved in Dec 2020 would be considered medical history (present prior to beginning of study)?' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:58:09
User closed query 'PV Query: Could you confirm if the subject was taking flonase, singulair, I-cap, Aleve, omega-3 fish oil, clindamycin, B12 supplement, calcium as concomitant medications?' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:58:04
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
Query 'PV Query: Could you confirm if subject's chronic cough that was noted to have resolved in Dec 2020 would be considered medical history (present prior to beginning of study)?' answered with 'Please advise where information of chronic cough is located?' (Site from Safety).	Angie Kean (b) (4) (b) (4)	29 Apr 2021 17:18:09
Query 'PV Query: Could you confirm if the subject was taking flonase, singulair, I-cap, Aleve, omega-3 fish oil, clindamycin, B12 supplement, calcium as concomitant medications?' answered with 'Site confirms subject is taking flonase and singulair as needed. Rx for Clindamycin is ONLY for prophylaxis dental work. I-cap ongoing daily. but was not taking supplements prior to study entry.' (Site from Safety).	Angie Kean (b) (4) (b) (4)	29 Apr 2021 17:17:53
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:00:53
User closed query 'Please finish narrative, per med records being received, FU on subject, etc.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 16:00:37

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Could you confirm if subject's chronic cough that was noted to have resolved in Dec 2020 would be considered medical history (present prior to beginning of study)? ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 12:40:06
User opened query 'PV Query: Could you confirm if the subject was taking flonase, singulair, I-cap, Aleve, omega-3 fish oil, clindamycin, B12 supplement, calcium as concomitant medications? ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 12:39:42
Query 'Please finish narrative, per med records being received, FU on subject, etc. ' answered with 'Narrative shortened due to character limitations in EDC. Please refer to source and medical records that were sent for complete narrative ' (Site from CRA).	Angie Kean (b) (4) (b) (4)	23 Apr 2021 16:27:15

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[Narrative](#)

Audit	User	Time (GMT)
User entered '81 y/o female presented at Urgent Care on 25FEB2021 with a cc of "worsening indigestion" that started on 24FEB2021. She completed a cardiac Echo on 01FEB2021. LVEF 60-65%. Subject sent to ED after an abnormal EKG reading of acute STEMI. Pain worsened and radiated to R arm and R shoulder blade. Given 324mg ASA and 0.09mg nitroglycerin. Second EKG reported normal sinus rhythm, occasional PVC, and new ST segment changes. Acute inferior infarct was interpreted. A CXR was obtained showed mild dependent atelectasis. Troponin T-Baseline value was high with results of 46. Troponin 2-HR was high with results of 240. A Troponin 6-HR was high with results of 911. LDL was 109 and Non HDL was 139. Subject had a negative COVID-19 PCR. CTA of chest showed no evidence of aortic aneurysm or pulmonary emboli. Subject taken to cath lab for catheterization where posterolateral branch of the right coronary artery was noted to be occluded. Heparin 4,000 units and nitroglycerin infusion 20mcg/min IV given. A 2.0x12mm balloon was used for angioplasty, but subject could not be stented due to small size and did not stay open despite several angioplasty attempts. Subject transferred to ICU with worsening pain under breasts and metallic taste in her mouth. An echo and EKG was completed on 26FEB2021 and confirmed cardiac stability. Subject given 1 nitroglycerin transdermal patch for discomfort. Subject was discharged in stable condition on 27FEB2021 with orders of aspirin 81 mg daily, atorvastatin 80mg daily at HS, famotidine 40mg daily, ticagrelor 90mg BID, and lidocaine 4% topical patch for back pain. Discharging physician stopped amlodipine 5 mg daily, estradiol 1 mg daily, and etodolac 400mg daily until her follow up visit on 03MAR21. Subject seen in our clinic for OLD57 and D209 visit. No changes in medications prescribed at discharge, but reports never utilized lidocane patch, therefore not reflected in conmeds' reason for change: New Information DataPoint Un-verified.	Angie Kean (b) (4) (b) (4)	23 Apr 2021 16:26:30
	Angie Kean (b) (4) (b) (4)	23 Apr 2021 16:01:34

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Signature has been broken.	Angie Kean (b) (4)	23 Apr 2021 16:01:34
	(b) (4)	
User entered empty; reason for change New Information	Angie Kean (b) (4)	23 Apr 2021 16:01:34
	(b) (4)	
User opened query 'Please finish narrative, per med records being received, FU on subject, etc. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 16:46:06
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
	(b) (4), (b) (6)	29 Mar 2021 18:48:17
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'TEST INFORMATION PROVIDED UNDER CONPROCEDURE LOG' (Site from Safety).	Angie Kean (b) (4)	26 Mar 2021 18:20:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:08:32
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)	09 Mar 2021 16:25:19
User entered 'Subject contacted study site on 01 MAR 2021 at 1740 regarding safety alert in ediary, at which time subject notified study staff she was admitted into ICU the week prior for a heart attack. No further information at this time, Medical records are being requested.'	Angie Kean (b) (4)	02 Mar 2021 18:17:19
	(b) (4)	

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 18:17:19

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Systolic murmur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:36:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:36:59
Data point term sent to Coder	System	08 Mar 2021 18:36:59
User entered 'grade 2 systolic heart murmur'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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Folder: Adverse Events

Form: Adverse Events (6)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '14 Jan 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Mar 2021 18:09:22
User entered '09:30' reason for change: New Information	Angie Kean (b) (4)	26 Mar 2021 18:09:22
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Mar 2021 18:36:01
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '14 Jan 2021 09:30'	System	26 Mar 2021 18:09:22
User entered empty.	System	08 Mar 2021 18:36:01

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Form: Adverse Events (6)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:27:21
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:27:23
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:27:26
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:36:01

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

US3812229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

US3812229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'I'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:27:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:36:01

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:14
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:27:37
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:26:50
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:36:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 18:36:01

US3812229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:52:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 18:36:01

US3812229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:39:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:39:42
Data point term sent to Coder	System	08 Mar 2021 18:39:00
User entered 'Coronary Artery Disease'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '25 Feb 2021'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:09
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:37:54
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:09
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:37:56
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:09
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:38:00
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:54
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:43:00
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	08 Mar 2021 18:38:18
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:52:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 18:38:18

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM). Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'SUBJECT HAS PRIOR MH OF HYPERLIPIDEMIA. PER INVESTIGATOR DIFFERENT CONDITIONS AND NOT WORSENING OF HYPERLIPIDEMIA' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 19:51:36
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	Anya Penly (b) (4) (b) (4)	07 Apr 2021 15:53:23
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type IIa hyperlipidaemia, LLT: Pure hypercholesterolemia - version MedDRA\23.0.	(b) (4), (b) (6)	04 Apr 2021 14:03:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:13:44
Data point term sent to Coder	System	17 Mar 2021 14:12:39
User entered 'Pure hypercholesterolemia'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Yes (Y)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'No (N)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'No (N)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '03 Mar 2021'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:05
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:47:13
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Yes (Y)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:05
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:47:14
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:39:05
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 16:47:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'No (N)'	Lylv Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'I'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered '0'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 16:31:58
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	21 Apr 2021 14:43:00
User entered empty.	Lyly Dang (b) (4) (b) (4)	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:52:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 14:12:28

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 19:06:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 19:06:50
Data point term sent to Coder	System	27 Apr 2021 17:48:56
User entered 'COVID LIKE ILLNESS'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '08 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:31:41
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 22:16:41
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:14:59
User closed query 'Please clarify end date, per Source query, 11Nov vs 12Nov, vs 17Nov?' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 22:14:57
Query 'Please clarify end date, per Source query, 11Nov vs 12Nov, vs 17Nov?' answered with 'updated' (Site from CRA).	Angie Kean (b) (4) (b) (4)	29 Apr 2021 17:22:44
User entered '17 Nov 2020' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	29 Apr 2021 17:22:37
User opened query 'Please clarify end date, per Source query, 11Nov vs 12Nov, vs 17Nov?' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 15:05:16
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 15:02:02
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '11 Nov 2020'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

None

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:59
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:52:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 17:48:44

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 19:08:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 19:08:09
Data point term sent to Coder	System	27 Apr 2021 17:50:03
User entered 'COVID LIKE ILLNESS'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '21 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Apr 2021 14:12:14
Query 'Data is required. Please provide.' answered with 'UNKNOWN ' (Site from System).	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:32
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Apr 2021 17:49:23
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '29 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Apr 2021 14:12:16
Query 'Data is required. Please provide.' answered with 'UNKNOWN PER SUB I' (Site from System).	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:45
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Apr 2021 17:49:23
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'I'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered '0'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	30 Apr 2021 02:45:57
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 14:38:55
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 17:49:23

US3812229

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:52:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Apr 2021 17:49:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:52:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:55
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 00:53:34
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:14:22
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	26 Mar 2021 17:56:04
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:12:19
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:12:14
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 17:01:17
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:52:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:50:32

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 19:53:36
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 Sep 2020 19:53:36
Data point term sent to Coder	System	06 Sep 2020 19:52:44
User entered 'LEVOTHYROXINE'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'HYPOTHYROIDISM'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:44:33
User entered '175' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:44:33
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered '200'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'ug (ug)' reason for change: Data Entry Error	Angie Kean (b) (4)	30 Oct 2020 23:35:22
User entered 'Other (OTHER)'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Please review "If dose unit is Other, specify" as there is an available option for "MCG" in the listed choices for unit (UG). Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 12:03:39
Query 'Per DM CLR: Please review "If dose unit is Other, specify" as there is an available option for "MCG" in the listed choices for unit (UG). Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	30 Oct 2020 23:35:27
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	30 Oct 2020 23:35:22
User opened query 'Per DM CLR: Please review "If dose unit is Other, specify" as there is an available option for "MCG" in the listed choices for unit (UG). Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 05:27:47
User entered 'MCG'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'once daily (QD)'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	06 Sep 2020 19:52:30
User entered 'Oral (ORAL)'	System	06 Sep 2020 19:51:46
	Karen Knapp (b) (4)	06 Sep 2020 19:51:46
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	06 Sep 2020 19:52:30
User entered 'UN'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'UN UNK 2005'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 19:51:46

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 15:01:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Oct 2020 15:01:17
Data point term sent to Coder	System	05 Oct 2020 00:04:29
Coding entries removed.	Angie Kean (b) (4)	05 Oct 2020 00:03:59
Coding entries removed.	Angie Kean (b) (4)	05 Oct 2020 00:03:59
User entered 'ESTRADIOL' reason for change: Data Entry Error	Angie Kean (b) (4)	05 Oct 2020 00:03:59
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 05:37:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 05:37:47
Data point term sent to Coder	System	06 Sep 2020 19:53:45
User entered 'ESSTRADIOL'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 08:50:25
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED PER QUERY' (Site from DM).	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:04:06
User entered 'HORMONE REPLACEMENT THERAPY DUE TO POST-MENOPAUSAL' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	05 Oct 2020 00:03:59
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 18:38:48
User entered 'HRT'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'l'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'mg (mg)'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	(b) (4) Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'once daily (QD)'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'UN UNK 2000'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:58
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:58
User entered '27 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
User entered '1'	System	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
User entered '1'	System	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:43
User entered '804 (804)'	System	06 Sep 2020 19:53:28

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 05:27:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 05:27:49
Data point term sent to Coder	System	06 Sep 2020 19:54:47
User entered 'CLOMAZEPAM'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:54:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Sep 2020 19:54:34
User entered 'RESTLESS LEG SYNDROME' reason for change: Data Entry Error	Karen Knapp (b) (4)	06 Sep 2020 19:54:34
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Sep 2020 19:54:16
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'I'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'mg (mg)'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'once daily (QD)'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'UN UNK 2015'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 19:54:16

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
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: ETODOLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:00:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:00:29
Data point term sent to Coder	System	28 Oct 2020 23:11:49
Coding entries removed.	Breanna Galibert (b) (4)	28 Oct 2020 23:11:27
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: ETODOLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 05:39:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 05:39:45
Data point term sent to Coder	System	06 Sep 2020 19:55:48
User entered 'ETODOLAC'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 09:47:26
Query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'UPDATED' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:11:35
User entered 'OSTEOARTHRITIS IN LOWER BACK' reason for change: Data Entry Error	Breanna Galibert (b) (4) (b) (4)	28 Oct 2020 23:11:27
User opened query 'Per DM CLR: Please update the indication to reflect the type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 19:53:48
User entered 'AARTHRTIS IN LOWER BACK'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '400'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'mg (mg)'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	(b) (4)	
	Karen Knapp (b) (4)	06 Sep 2020 19:55:30
	(b) (4)	

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'twice daily (BID)'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'UN UNK 2010'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:44:15
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:44:15
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:44:15
User entered '27 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:44:15
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Karen Knapp (b) (4) (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Karen Knapp (b) (4)	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
User entered '2'	System	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
User entered '1'	System	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:46
User entered '804 (804)'	System	06 Sep 2020 19:55:30

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 19:28:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 19:28:43
Data point term sent to Coder	System	21 Sep 2020 19:28:11
User entered 'FLONASE'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'SEASONAL ALLERGIES'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'I'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Other (OTHER)'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'MIST'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
User closed query 'Please clarify as the Source notes PRN. ' (Site from CRA).	(b) (4), (b) (6)	31 Mar 2021 18:57:02
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:56:57
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
Query 'Please clarify as the Source notes PRN. ' answered with 'updated' (Site from CRA).	Angie Kean (b) (4)	26 Mar 2021 17:57:17
Signature has been broken.	Angie Kean (b) (4)	26 Mar 2021 17:57:11
User entered 'as needed (PRN)' reason for change: Data Entry Error	Angie Kean (b) (4)	26 Mar 2021 17:57:11
User opened query 'Please clarify as the Source notes PRN. ' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 15:29:13
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 15:28:55
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'once daily (QD)'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Nasal (NASAL)'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'UN UNK 2016'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:57:11
User entered '1'	System	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4) (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4) (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:57:11
User entered '1'	System	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4) (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4) (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 17:57:11
User entered '804 (804)'	System	21 Sep 2020 19:27:17
DataPoint activated with code reason code Data required.	Angie Kean (b) (4) (b) (4)	21 Sep 2020 19:26:03
DataPoint inactivated with code reason code Data not required.	Breanna Galibert (b) (4) (b) (4)	09 Sep 2020 17:13:57

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 19:28:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 19:28:43
Data point term sent to Coder	System	21 Sep 2020 19:28:12
User entered 'AMLODIPINE'	Angie Kean (b) (4) (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'HYPERTENSION'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '5'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'mg (mg)'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'once daily (QD)'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'UN UNK 2015'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:33
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:33
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:33
User entered '27 Feb 2021' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:33
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4) (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
User entered '1'	System	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
User entered '1'	System	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:54
User entered '804 (804)'	System	21 Sep 2020 19:27:53

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 08:41:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 08:41:08
Data point term sent to Coder	System	02 Nov 2020 18:34:13
User entered 'tylenol'	Any Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	(b) (4) Any Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened (MH# 4 ARTHRITIS IN LOWER BACK). If yes, please review if an AE of Worsening LOW BACK PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:04:06
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened (MH# 4 ARTHRITIS IN LOWER BACK). If yes, please review if an AE of Worsening LOW BACK PAIN should be recorded, and update con med indication or provide clarification. ' answered with 'confirmed with subject was NOT worsening in condition' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:03:11
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened (MH# 4 ARTHRITIS IN LOWER BACK). If yes, please review if an AE of Worsening LOW BACK PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 07:55:53
User entered 'low back pain'	Anya Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '325'	(b) (4) Any Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'mg (mg)'	(b) (4) Any Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	(b) (4)	
	Any Penly (b) (4)	02 Nov 2020 18:33:34
	(b) (4)	

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:33:06
DataPoint Un-verified.	(b) (4), (b) (6)	17 Mar 2021 15:32:43
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'as needed (PRN)'	(b) (4)	
	Any Penly (b) (4)	02 Nov 2020 18:33:34
	(b) (4)	

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	(b) (4)	
	Any Penly (b) (4)	02 Nov 2020 18:33:34
	(b) (4)	

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	(b) (4) Any Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	(b) (4)	
	Any Penly (b) (4)	02 Nov 2020 18:33:34
	(b) (4)	

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '4 Sep 2020'	(b) (4) Any Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Any Penly (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	(b) (4) Any Penly (b) (4) (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '4 Sep 2020'	Any Penly (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Any Penly (b) (4)	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
User entered empty.	System	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
User entered empty.	System	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:05
User entered empty.	System	02 Nov 2020 18:33:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 19:12:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 19:12:28
Data point term sent to Coder	System	27 Apr 2021 17:52:12
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:51:29
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:13:50
Data point term sent to Coder	System	10 Nov 2020 20:13:19
User entered 'TYLENOL'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 22:17:51
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:35:08
DataPoint Un-verified.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:51:29
Signature has been broken.	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:51:29
User entered 'COVID LIKE ILLNESS' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	27 Apr 2021 17:51:29
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 14:04:18
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'symptom reported during illness convalescent period, not AE' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:04:07
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 07:56:08
User entered 'HEADACHE'	Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '325'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'mg (mg)'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '08 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '08 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given beyond day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:55:59
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given beyond day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' answered with 'updated. was not solicited, reported during illness. NO criteria for AE' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Feb 2021 13:51:16
Signature has been broken.	Angie Kean (b) (4) (b) (4)	23 Feb 2021 13:50:57
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Feb 2021 13:50:57
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of HEADACHE in eDiary. Please note that this CM was given beyond day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:34:33
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Angie Kean (b) (4)	20 Jan 2021 17:03:47
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
User entered empty.	System	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
User entered empty.	System	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:06
User entered empty.	System	10 Nov 2020 20:13:15

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
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)	10 Nov 2020 20:15:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 20:15:40
Data point term sent to Coder	System	10 Nov 2020 20:14:23
User entered 'INFLUENZA VACCINE'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'FLU PREVENTATIVE'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'I'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'DOSE'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'once (ONCE)'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Breanna Galibert (b) (4) (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '03 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '03 Nov 2020'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
User entered empty.	System	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
User entered empty.	System	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:10
User entered empty.	System	10 Nov 2020 20:14:14

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:53:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 16:53:31
Data point term sent to Coder	System	12 Nov 2020 16:52:32
User entered 'SENOKOT'	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:56:40
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'medical history log line 35' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Feb 2021 13:53:13
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:34:46
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'CONSTIPATION'	Breanna Galibert (b) (4) (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:05:27
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:10:36
User entered '15' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:10:30
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 08:00:31
User entered '60'	Breanna Galibert (b) (4) (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'mg (mg)'	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '08 Nov 2020'	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE 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)	22 Jan 2021 14:05:38
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:10:44
User entered 'No (N)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:10:30
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE 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)	04 Jan 2021 08:00:39
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '18 Nov 2020' reason for change: New Information	Angie Kean (b) (4)	20 Jan 2021 17:10:30
User entered empty.	Breanna Galibert (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 14:05:42
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:10:48
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	20 Jan 2021 17:10:30
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 08:00:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
User entered empty.	System	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
User entered empty.	System	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:12
User entered empty.	System	12 Nov 2020 16:51:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: MINERALS NOS;VITAMINS NOS, PRODUCTSYNONYM: ICAPS [MINERALS NOS;VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 09:52:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 09:52:12
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
Data point term sent to Coder	System	19 Feb 2021 20:22:12
User entered 'iCAPS'	Angie Kean (b) (4) (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:38:51
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	09 Mar 2021 23:22:07
Signature has been broken.	Angie Kean (b) (4) (b) (4)	09 Mar 2021 23:21:53
User entered 'No (N)' reason for change: Per Query Resolution	Angie Kean (b) (4) (b) (4)	09 Mar 2021 23:21:53
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 13:03:52
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'GLAUCOMA'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'I'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'tablet (TABLET)'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'twice daily (BID)'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Oral (ORAL)'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'UN UNK 2018'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered '0'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'No (N)'	Angie Kean (b) (4)	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 20:21:23

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:42:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:42:40
Data point term sent to Coder	System	08 Mar 2021 18:42:05
User entered 'aspirin'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Coronary Artery Disease'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '81'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '28 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Mar 2021 18:41:22

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:42:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:42:40
Data point term sent to Coder	System	08 Mar 2021 18:42:05
User entered 'brilinta'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Coronary Artery Disease'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '90'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'twice daily (BID)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '28 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Mar 2021 18:41:45

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:43:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:43:45
Data point term sent to Coder	System	08 Mar 2021 18:43:06
User entered 'atorvastatin'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Coronary Artery Disease'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '80'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'once daily (QD)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '28 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Mar 2021 18:42:37

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:42:41
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GASTROESOPHAGEAL REFLUX DISEASE worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 16:22:38
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GASTROESOPHAGEAL REFLUX DISEASE worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'DOES NOT MEET AE CRITERIA AS NOT FOR WORSENING GERD' (Site from DM).	Anya Penly (b) (4) (b) (4)	07 Apr 2021 15:48:16
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:18:30
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GASTROESOPHAGEAL REFLUX DISEASE worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:00:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 18:44:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 18:44:45
Data point term sent to Coder	System	08 Mar 2021 18:44:06
User entered 'famotidine'	Breanna Galibert (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'gastroesophageal reflux disease'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '40'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '27 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 18:43:06

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:38:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:38:58
Data point term sent to Coder	System	10 Mar 2021 21:37:44
User entered 'aspirin'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'MYOCARDIAL INFARCTION'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '324'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User entered empty.	System	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User entered empty.	System	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:24
User entered empty.	System	10 Mar 2021 21:37:00

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:39:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 21:39:56
Data point term sent to Coder	System	10 Mar 2021 21:38:46
User entered 'nitroglycerin'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'MYOCARDIAL INFARCTION'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:44:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	16 Apr 2021 18:29:29
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 16:07:53
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' answered with 'CORRECTED DOSAGE' (Site from DM).	Anya Penly (b) (4) (b) (4)	07 Apr 2021 15:58:19
DataPoint Un-verified.	Anya Penly (b) (4) (b) (4)	07 Apr 2021 15:58:03
Signature has been broken.	Anya Penly (b) (4) (b) (4)	07 Apr 2021 15:58:03
User entered '0.9' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	07 Apr 2021 15:58:03
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 19:20:35
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:19:57
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:00:53
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.09'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'sublingual'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User entered empty.	System	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User entered empty.	System	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:26
User entered empty.	System	10 Mar 2021 21:37:51

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:58:30
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:20
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
Data point term sent to Coder	System	26 Mar 2021 18:08:05
DataPoint Un-verified.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:07:06
Coding entries removed.	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:07:06
User entered 'HEPARIN' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	26 Mar 2021 18:07:06
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:30:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 08:30:59
Data point term sent to Coder	System	10 Mar 2021 21:38:44
User entered 'hepann'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'MYOCARDIAL INFARCTION'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '4000'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'units'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Intravenous (INTRAVENOUS)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User entered empty.	System	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User entered empty.	System	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:27
User entered empty.	System	10 Mar 2021 21:38:34

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:49:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:49:43
Data point term sent to Coder	System	10 Mar 2021 21:39:47
User entered 'nitroglycerin'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'MYOCARDIAL INFARCTION'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '20'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'ug (ug)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Intravenous (INTRAVENOUS)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '25 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User entered empty.	System	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User entered empty.	System	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:29
User entered empty.	System	10 Mar 2021 21:39:13

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:46:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:46:41
Data point term sent to Coder	System	10 Mar 2021 21:40:47
User entered 'nitroglycerin patch'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:44:43
DataPoint Un-verified.	(b) (4), (b) (6)	31 Mar 2021 19:22:30
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'cad'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'l'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Other (OTHER)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'unk'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'once (ONCE)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'Transdermal (TRANSDERMAL)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '26 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '0'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered '26 Feb 2021'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:23:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User entered empty.	System	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User entered empty.	System	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:32
User entered empty.	System	10 Mar 2021 21:39:55

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:01:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 08:01:05
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:58:56
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:55:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:56:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 17:56:28
Data point term sent to Coder	System	26 Mar 2021 17:55:34
User entered 'botox'	Angie Kean (b) (4) (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:58:58
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'Yes (Y)'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'wrinkle prevention'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:03
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered '10'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:08
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'Other (OTHER)'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:11
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'units'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'once (ONCE)'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:27
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered empty.	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'Subcutaneous (SUBCUTANEOUS)'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:37
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered empty.	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'un UNK 2017'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered '0'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:48
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'No (N)'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:53
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'un UNK 2017'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 18:59:55
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:55:20
User entered 'No (N)'	Angie Kean (b) (4)	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
User entered empty.	System	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
User entered empty.	System	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:52:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:33:34
User entered empty.	System	26 Mar 2021 17:55:33

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:52:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:55
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:20:57
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User entered 'No (N)'	Anya Penly (b) (4)	12 Nov 2020 22:17:33
	(b) (4)	
	Karen Knapp (b) (4)	03 Sep 2020 17:08:17
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	23 Apr 2021 21:55:48
Signature has been broken.	Angie Kean (b) (4) (b) (4)	23 Apr 2021 17:20:16
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:18:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Larkin Wadsworth (b) (4) (b) (4)	20 Feb 2021 23:28:54
User entered '7 Sep 2020'	Anyia Penly (b) (4) (b) (4)	12 Nov 2020 22:18:05

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:18:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'removal of foreign body'	Any Penly (b) (4)	12 Nov 2020 22:18:05

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:18:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered 'Adverse Event (AE)'	Any Penly (b) (4)	12 Nov 2020 22:18:05

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:18:07
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 23:28:54
User entered empty.	Any Penly (b) (4)	12 Nov 2020 22:18:05

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:07:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '25 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:02

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:07:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Balloon Angioplasty'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:02

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:07:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:02

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:41
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:07:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:02

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '25 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:37

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'EKG'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:37

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:37

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:51
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:52:37

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '25 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:22

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Repeat EKG'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:22

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:22

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:47
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:22

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:14:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '25 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:56

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:14:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'CHEST XRAY'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:56

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:14:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:56

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:14:41
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:53:56

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:36:36
Query 'Please clarify location of procedure in med records. ' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:36:34
User opened query 'Please clarify location of procedure in med records. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:35:32
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '25 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:54:54

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:54
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:55:20
User closed query 'Please add Influenza A/B and RSV, and other lab panels, as they were included in panel, per med records. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:55:17
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	23 Apr 2021 21:55:48
Query 'Please add Influenza A/B and RSV, and other lab panels, as they were included in panel, per med records. ' answered with 'updated procedures excluding laboratory testing as discussion with CRA, (b) (6) and (b) (6) not required. ' (Site from CRA).	Angie Kean (b) (4) (b) (4)	23 Apr 2021 17:04:15
Signature has been broken.	Angie Kean (b) (4) (b) (4)	23 Apr 2021 16:10:05
User entered 'PRE SURGICAL REQUIRED COVID PCR, NEGATIVE.' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Apr 2021 16:10:05
User opened query 'Please add Influenza A/B and RSV, and other lab panels, as they were included in panel, per med records. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:40:28
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:36:50
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:36:37
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'PRE SURGICAL REQUIRED COVID PCR, NEGATIVE'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:54:54

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:36:39
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:54:54

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:36:40
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:54:54

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:04:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '25 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:03

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:04:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'COMPUTERIZED TOMOGRAPHY ANGIOGRAPHY'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:03

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:04:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:03

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:58
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:04:11
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:03

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '26 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:38

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'EKG'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:38

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:38

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:12:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:56:38

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:07
User closed query 'Please add Cardiac Echo, which occurred on 25Feb2021, per med records. ' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 15:56:21
Query 'Please add Cardiac Echo, which occurred on 25Feb2021, per med records. ' answered with 'added per query' (Site from CRA).	Angie Kean (b) (4) (b) (4)	23 Apr 2021 16:30:34
User opened query 'Please add Cardiac Echo, which occurred on 25Feb2021, per med records. ' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:17:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:17:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered '26 Feb 2021'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:59:00

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:17:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'CARDIAC ECHO'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:59:00

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:17:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered 'Adverse Event (AE)'	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:59:00

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:07
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:17:05
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 17:03:43
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:53:36
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
User entered empty.	lauren clement (b) (4) (b) (4)	18 Mar 2021 21:59:00

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:33
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered '25 Feb 2021'	Angie Kean (b) (4)	23 Apr 2021 16:31:29
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:35
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered 'Influenza A/B'	Angie Kean (b) (4)	23 Apr 2021 16:31:29
	(b) (4)	

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:37
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered 'Adverse Event (AE)'	Angie Kean (b) (4)	23 Apr 2021 16:31:29
	(b) (4)	

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:16
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:57:39
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	23 Apr 2021 16:31:29
	(b) (4)	

US3812229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:52:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:20
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:15
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered '25 Feb 2021'	Angie Kean (b) (4)	23 Apr 2021 16:31:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:52:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:20
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:15
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered 'RSV'	Angie Kean (b) (4)	23 Apr 2021 16:31:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:52:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:20
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:15
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered 'Adverse Event (AE)'	Angie Kean (b) (4)	23 Apr 2021 16:31:52
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 10 Jun 2021 09:52:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:20
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:15
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 21:55:48
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	23 Apr 2021 16:31:52
	(b) (4)	

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:52:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
User entered '03/Mar/2021 10:49'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:52:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:52:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
User entered '09/Mar/2021 11:47'	System	09 Mar 2021 17:47:52

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:52:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 17:47:52

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lylv Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:52:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
User entered '10/Mar/2021 08:55'	System	10 Mar 2021 13:55:31

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:52:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 13:55:31

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:52:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
User entered '11/Mar/2021 09:16'	System	11 Mar 2021 14:16:56

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:52:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 14:16:56

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:52:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:09
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
User entered '29/Mar/2021 14:49'	System	29 Mar 2021 18:49:01

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:52:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:09
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 18:49:01

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:52:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:35:08
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:09
User entered '26/Apr/2021 11:47'	System	26 Apr 2021 15:47:27

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:52:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 15:58:21
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	28 Apr 2021 13:35:08
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:09
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 15:47:27

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'USA-US111-2021-MRNA-1273-P301000012'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Death

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Yes (Y)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'No (N)'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:02
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'lauren'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Lyly'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Larkin'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:59:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'clement'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered 'Dang'	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'Wadsworth'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '711 Old Ballas Rd Suite 105'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered 'St Louis'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 15:58:59
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:47:06
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	08 Apr 2021 01:40:47
Un-reviewed for Safety.	System	29 Mar 2021 18:49:01
DataPoint Un-verified.	System	29 Mar 2021 18:49:01
Signature has been broken.	System	29 Mar 2021 18:49:01
User entered 'MO'	System	29 Mar 2021 18:49:01
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:16:33
Un-reviewed for Safety.	System	09 Mar 2021 17:47:52
User entered empty.	System	09 Mar 2021 17:47:52
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'MISSOURI'	lauren clement (b) (4) (b) (4)	08 Mar 2021 16:37:03

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 14:17:02
Un-reviewed for Safety.	System	11 Mar 2021 14:16:56
User entered empty.	System	11 Mar 2021 14:16:56
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:49:12
User entered '63141'	System	03 Mar 2021 16:49:00

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 20:54:21
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 14:43:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:47:32
User entered 'US'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 15:58:29
User entered '6'	System	26 Apr 2021 15:47:27
User entered '5'	System	29 Mar 2021 18:49:01
User entered '4'	System	11 Mar 2021 14:16:56
User entered '3'	System	10 Mar 2021 13:55:31
User entered '2'	System	09 Mar 2021 17:47:52
User entered '1'	System	03 Mar 2021 16:49:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:52:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	01 May 2021 20:47:48
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:12:51
User entered '30/Apr/2021 11:58'	System	30 Apr 2021 15:58:29

US3812229

Folder: SAE USA-US111-2021-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:52:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	01 May 2021 20:47:48
DataPoint Verified.	(b) (4), (b) (6)	01 May 2021 03:12:51
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 15:58:29