

US3412224 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:33:31

All time stamps listed in this document are displayed in GMT

US3412224

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:45:38

Generated On: 11 Aug 2021 22:33:31

[Participant ID](#)

US3412224

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

US3412224

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3412224

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	54
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) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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

US3412224

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412224

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	ALLERGIC RHINITIS - SEASONAL
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	GASTROESOPHAGEAL REFLUX DISEASE
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)	

US3412224

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412224

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	BILATERAL DIPLOPIA
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3412224

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	IDIOPATHIC THROMBOCYTOPENIC PURPURA (STABLE)
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 (7)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	ESSENTIAL TREMORS IN BILATERAL HANDS AND NECK
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	ALERGIC TO PENICILLIN
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 (11)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	ALERGIC TO SULFA DRUGS
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 (12)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	ALERGIC TO NAPROXEN
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 (13)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	TMJ SURGERY
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	RIGHT SHOULDER SURGERY (BURSITIS)
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	TMJ DISORDER
Start date (dd MMM yyyy)	UN UNK 1988
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 1988
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1988
Stop Year (derived)	1988

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	POST -MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Condition	BURSITIS
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3412224

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:29 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 09:29
Height (<i>xxx.x</i>)	166.4 cm
Weight (<i>xxx.x</i>)	85.4 kg
BMI (<i>xxx.x</i>)	30.84262 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	48 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412224

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Date of assessment (dd MMM yyyy) 13 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 2004

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 104289

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Height	167 cm
Weight	84.8 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Height	167 cm
Weight	84.8 kg
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:11 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:11
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Height	167 cm
Weight	84.8 kg
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	13:31 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 13:31
Temperature (xxx.x)	96.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

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) 14 AUG 2020

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

Treatment Date and Time (derived) 14 AUG 2020 13:00

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

US3412224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	12:36 (24 HR)
Collection date and time (derived)	14 AUG 2020 12:36

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:41	14 AUG 2020 12:41
Nasopharyngeal Swab 2	No		

US3412224

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 13:37

PC Open Date & Time

14 AUG 2020 13:20

PC Close Date & Time

14 AUG 2020 15:50

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

96.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp	14 AUG 2020 19:37
PC Open Date & Time	14 AUG 2020 16:45
PC Close Date & Time	15 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:37

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:03

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 20:48

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

96.4 °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

18 AUG 2020 18:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

96.0 °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 AUG 2020 20:26

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

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.

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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

20 AUG 2020 20:20

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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 ☐

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

5

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 13:40

PC Open Date & Time

14 AUG 2020 13:20

PC Close Date & Time

14 AUG 2020 15:50

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

14 AUG 2020 19:41

PC Open Date & Time

14 AUG 2020 16:45

PC Close Date & Time

15 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

15 AUG 2020 19:39

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

16 AUG 2020 20:06

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

17 AUG 2020 20:50

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

18 AUG 2020 18:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

19 AUG 2020 20:28

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

20 AUG 2020 20:21

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 13:41
PC Open Date & Time	14 AUG 2020 13:20
PC Close Date & Time	14 AUG 2020 15:50

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 19:43
PC Open Date & Time	14 AUG 2020 16:45
PC Close Date & Time	15 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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)

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:40
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:07
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 20:52
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

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 ☒

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:29
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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)

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 20:22
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3412224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	09:04 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:04
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 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)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

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)	11 SEP 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:25
Temperature (xxx.x)	95.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:50 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 09:50

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

US3412224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

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

Collection date (dd MMM yyyy)	11 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	09:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	11 SEP 2020 09:20
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US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:18	11 SEP 2020 09:18
Nasopharyngeal Swab 2	No		

US3412224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 10:27

PC Open Date & Time

11 SEP 2020 10:10

PC Close Date & Time

11 SEP 2020 12:40

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	11 SEP 2020 20:11
PC Open Date & Time	11 SEP 2020 13:35
PC Close Date & Time	12 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 20:04

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 20:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

97.5 °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

15 SEP 2020 06:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

96.4 °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

15 SEP 2020 19:54

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:20

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

96.0 °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

17 SEP 2020 20:00

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

11 SEP 2020 10:28

PC Open Date & Time

11 SEP 2020 10:10

PC Close Date & Time

11 SEP 2020 12:40

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 20:11

PC Open Date & Time

11 SEP 2020 13:35

PC Close Date & Time

12 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 20:05

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 20:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

15 SEP 2020 06:37

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 19:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 20:21

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 20:00

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 10:29
PC Open Date & Time	11 SEP 2020 10:10
PC Close Date & Time	11 SEP 2020 12:40

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:13
PC Open Date & Time	11 SEP 2020 13:35
PC Close Date & Time	12 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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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US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 20:06
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

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 ☒

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 20:08
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

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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Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:37
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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 ☒

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:56
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

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 ☒

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:21
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 20:01
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3412224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:59:12

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:47:54

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

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.

US3412224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 OCT 2020
Collection time (00:00-23:59)	09:15 (24 HR)
Collection date and time (derived)	07 OCT 2020 09:15

US3412224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:47:55

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 OCT 2020 12:51:03
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

22 OCT 2020 07:04:22

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 20:04:12
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 06:24:40
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 06:31:42

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 NOV 2020 08:23:32
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 DEC 2020 16:46:20
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 DEC 2020 09:43:01
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 19:09:34
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 DEC 2020 18:03:58

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

27 DEC 2020 07:19:30

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 00:35:33

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

10 JAN 2021 08:05:25

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 17:55:37
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 00:05:57
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

31 JAN 2021 00:03:14

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 02:31:50
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 21:58:27
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 01:54:48

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 15:16:29

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

07 MAR 2021 00:02:49

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

14 MAR 2021 21:28:26

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 MAR 2021 20:00:54
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

28 MAR 2021 09:22:32

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

04 APR 2021 21:36:14

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

11 APR 2021 18:48:36

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

18 APR 2021 00:02:40

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

25 APR 2021 10:27:54

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	02 MAY 2021 08:16:10
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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="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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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="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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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="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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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07 APR 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

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21 APR 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

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28 APR 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

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02 JUN 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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°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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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="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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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 <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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3412224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:33:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 14:06:43

US3412224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:37:04

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:37:04

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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 WAS IN
CONVALESCENT PHASE OF THE
STUDY AND THEREFOR NO
CONTACT WAS ATTEMPTED.

US3412224

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT4

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 15:20
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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.

US3412224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	15:36 (24 HR)
Collection date and time (derived)	09 MAR 2021 15:36

US3412224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 14:45:39

Generated On: 11 Aug 2021 22:33:31

Date of Contact	25 NOV 2020
Time of Contact	09:54
Date and Time of Contact (derived)	25 NOV 2020 09:54
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>

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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"/>

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 25 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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 checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 25 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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

Date	25 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	36.8 C
-------------	--------

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

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

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

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

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Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 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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Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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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Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	99.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 type="radio"/>
	Mild	<input checked="" 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) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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	1 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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"/>

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 type="checkbox"/>
Day 10	<input checked="" 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"/>

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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	2 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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"/>

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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

Date	26 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

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

Temperature	
-------------	--

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98.2 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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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 NOV 2020
------	-------------

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

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

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

Temperature	98.9 F
-------------	--------

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

Cough	None <input type="radio"/>
	Mild <input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

Symptom Day

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

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.7 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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	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (10)

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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 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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Form: Symptom Log (11)

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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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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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	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	3 DEC 2020
------	------------

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

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

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

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

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

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

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

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

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	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"/>

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Form: Symptom Log (11)

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Generated On: 11 Aug 2021 22:33:31

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 (12)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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 (12)

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Generated On: 11 Aug 2021 22:33:31

	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	4 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	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"/>

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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 (13)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" 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 (13)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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	5 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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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Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 checked="" 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 (14)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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	6 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	95.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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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Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 25 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 checked="" 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 25 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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	7 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 25 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 25 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

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 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 checked="" 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 25 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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	8 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

	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 25 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:42:00

Generated On: 11 Aug 2021 22:33:31

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 14:45:38

Generated On: 11 Aug 2021 22:33:31

Date of Visit	25 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 checked="" type="radio"/> No <input type="radio"/>
Date of Test	25 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)	1

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:45:39

Generated On: 11 Aug 2021 22:33:31

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 30 NOV 2020

End Date 30 NOV 2020

Oxygen Saturation 93 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:45:39

Generated On: 11 Aug 2021 22:33:31

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:45:39

Generated On: 11 Aug 2021 22:33:31

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 14:45:39

Generated On: 11 Aug 2021 22:33:31

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	27 NOV 2020
Day 5	Yes	29 NOV 2020
Day 7	Yes	01 DEC 2020
Day 9	Yes	03 DEC 2020
Day 14	Yes	08 DEC 2020
Day 21	Yes	15 DEC 2020
Day 28	No	

US3412224

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	09:54 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 09:54
Height (xxx.x)	166.4 cm
Weight (xxx.x)	84.8 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412224

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3412224

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

25 NOV 2020

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:45:38

Generated On: 11 Aug 2021 22:33:31

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:45:38

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:45:38

Generated On: 11 Aug 2021 22:33:31

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.

US3412224

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 14:45:38

Generated On: 11 Aug 2021 22:33:31

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

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3412224

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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

Visit date (dd MMM yyyy)	12 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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US3412224

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Date of updated informed consent (<i>dd MMM yyyy</i>)	30 DEC 2020
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>)	30 DEC 2020
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

US3412224

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Height	166 cm
Weight	90.7 kg
BMI (xxx.x)	32.91479

US3412224

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Height	166 cm
Weight	90.7 kg
BMI (xxx.x)	32.91479
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)	12 JAN 2021
Time of assessment (00:00-23:59)	15:31 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 15:31
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412224

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Height	166 cm
Weight	90.7 kg
BMI (xxx.x)	32.91479
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)	12 JAN 2021
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 16:15
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412224

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3412224

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 15:45 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 15:45

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

US3412224

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00-23:59)	15:35 (24 HR)
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Collection date and time (derived)	12 JAN 2021 15:35
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US3412224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	15:32
Collection Date and Time (derived)	12 JAN 2021 15:32

US3412224

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:37:04

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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)	09 FEB 2021
Time of assessment (00:00-23:59)	10:22 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 10:22
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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)	09 FEB 2021
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	09 FEB 2021 11:38
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412224

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 FEB 2021

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

US3412224

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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) 09 FEB 2021

What was the treatment time? (00:00-23:59) 11:06 (24 HR)

Treatment Date and Time (derived) 09 FEB 2021 11:06

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

US3412224

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:37:04

Generated On: 11 Aug 2021 22:33:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:37:04

Generated On: 11 Aug 2021 22:33:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412224

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	15:20 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 15:20
Temperature (<i>xxx.x</i>)	36.5 C
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>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412224

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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.

US3412224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

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

Collection date (dd MMM yyyy)	09 MAR 2021
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Collection time (00:00-23:59)	15:36 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	09 MAR 2021 15:36
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US3412224

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:36:31

Generated On: 11 Aug 2021 22:33:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

AEID

Adverse event

INFECTED RIGHT INDEX
FINGER

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

17 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

AEID	USA-US061-2020-MRNA-1273-P30 1000020
Adverse event	SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	23 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)	08 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

SUBJECT STATED A COUGH,
NASAL CONGESTION, AND
HEADACHE ON 23-NOV-2020.
HER SYMPTOMS WERE MILD.
SHE FEELS THEY HAVE
WORSENERED AND NOW MILD TO
MODERATE. SHE DENIES
FEVER, CHILLS, NAUSEA,
NAUSEA, VOMITING, AND
DIARRHEA. NO PROCEDURES
OR CON MEDS WERE ADDED.
SUB-I AND PI CONFIRM MILD
AE.

SUBJECT TOOK 1 TAB BID OF
SUDAFED 24NOV2020 AND 25
NOV2020 AND WILL CONTINUE
TO TAKE AS NEEDED.

SUBJECT TOOK A RAPID
RESULTS TEST AT WORK,
WHICH RETURNED POSITIVE
(30NOV2020).

01DEC2020 - SUBJECT STILL
EXPERIENCING
MILD-MODERATE SYMPTOMS.

02DEC2020 - SUBJECT STILL
EXPERIENCING
MILD-MODERATE SYMPTOMS
BUT IS FEELING OK.

03DEC2020 - SUBJECT FEELS
BETTER, STILL HAS SOME MILD
SYMPTOMS.

08DEC2020 - SUBJECT IS
FEELING BETTER WITH NO
SYMPTOMS.

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 (3)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

AEID	
Adverse event	VERTIGO
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	7 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

AEID	
Adverse event	ATTENTION DEFICIT DISORDER
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)	18 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

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

Yes ☒

No ☐

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

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐
No ☒

Indication ESSENTIAL TREMORS

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication FLUOXETINE - PROZAC

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 50 TO 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication FOLIC ACID

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

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 (4)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication PREMARIN

Prophylaxis Yes ☐
No ☒

Indication HORMONE REPLACEMENT FOR
HYSTERECTOMY

Dose per administration .625

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 (5)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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 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 (6)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication EMGALITY

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 20

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

If dose unit is Other, specify MG/ML

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) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" 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 (7)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication PHENTERMINE

Prophylaxis Yes ☐
No ☒

Indication WEIGHT LOSS

Dose per administration 37.5

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 (7)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication ZANTAC

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 150

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 (8)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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)	09 JAN 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 (9)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication IBANDRONATE SODIUM

Prophylaxis Yes ☐
No ☒

Indication OSTEOPOROSIS

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication BACLOFEN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication CO-Q-10

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication VITAMIN B-2

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication MELATONIN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 10000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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 2004
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 (17)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication VITAMIN B-6

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

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 (19)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication COLLAGEN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication SEMATRIPTAN INJECTION

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 6

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 (21)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (22)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication MAXALT

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (23)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 600-800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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 2005	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication INFECTION - RIGHT INDEX
FINGER

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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)	18 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	INFLUENZA PROPHYLAXIS
------------	-----------------------

Dose per administration	0.5
-------------------------	-----

Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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)		25 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 SEP 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"/>

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication MECLIZINE

Prophylaxis Yes ☐
No ☒

Indication VERTIGO

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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)	5 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	7 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication SUDAFED 12 HOUR

Prophylaxis Yes ☐
No ☒

Indication URI / COVID-19

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 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)	28 NOV 2020	
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"/>

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	10 JAN 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"/>

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

Name of Medication STRATTERA

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 13:31:38

Generated On: 11 Aug 2021 22:33:31

	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 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:40:11

Generated On: 11 Aug 2021 22:33:31

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 11 Aug 2021 22:33:31

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3412224

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:33:31

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

US3412224

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:33:31

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 ☐

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US061-2020-MRNA-1273-P301000020
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US061-2020-MRNA-1273-P301000020
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/DEC/2020 17:39
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

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US061-2020-MRNA-1273-P301000020
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	17/MAR/2021 18:09
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

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:46:52

Generated On: 11 Aug 2021 22:33:31

SAEID	USA-US061-2020-MRNA-1273-P301000020
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/MAR/2021 11:52
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

US3412224 (Prod: New Horizons Clinical Research)

US3412224

Form: Participant Creation

Generated On: 11 Aug 2021 22:33:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:23:46
User entered 'US3412224'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:34:35

US3412224

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:07:53
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 16:59:44

US3412224

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:07:53
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	19 Aug 2020 19:26:49
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	14 Aug 2020 17:00:38
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:34:37

US3412224

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:07:53
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	14 Aug 2020 16:59:44

US3412224

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'SCRN'	System	14 Aug 2020 16:59:44

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:34:38

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '54'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'YEARS'	System	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '54'	System	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered 'Female (F)'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered 'l'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered empty.	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:33:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:09
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 17:00:18

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:21
User entered '13 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 19:26:49
User entered '14 Aug 2020'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Aug 2020'	System	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2020'	System	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:21
User entered 'Amendment 2 (2)'	Steven Anderson (b) (4)	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:21
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:21
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:21
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:21
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:38

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:21
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 13:34:37

US3412224

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:33:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'I'	System	14 Aug 2020 17:00:44

US3412224

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:33:31

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:32
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:44

US3412224

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:33:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:08:38
User entered 'Yes (Y)'		19 Aug 2020 18:57:12

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:41:18
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:44:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:44:30
Data point term sent to Coder	System	12 Oct 2020 17:43:49
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:43:30
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:43:30
User entered 'ALLERGIC RHINITIS - SEASONAL' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:43:30
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:58:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 18:58:24
Data point term sent to Coder	System	19 Aug 2020 18:58:04
User entered 'SEASONAL ALLERGIC RHINITIS'	(b) (4), (b) (6)	19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 1975'		19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'		19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'		19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
Signature has been broken.	Steven Anderson (b) (4)	16 Mar 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.		19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'		19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1975'	System	19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1975'	System	19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:57:37

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:41
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) (b) (4)	19 Aug 2020 19:00:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:00:25
Data point term sent to Coder	System	19 Aug 2020 18:59:07
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 2010'		19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'		19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'		19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.		19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'		19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2010'	System	19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2010'	System	19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:58:23

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:41
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:00:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:00:25
Data point term sent to Coder	System	19 Aug 2020 18:59:08
User entered 'DEPRESSION'	(b) (4), (b) (6)	19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 1995'		19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'		19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'		19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'		19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1995'	System	19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1995'	System	19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:59:01

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:41
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) (b) (4)	19 Aug 2020 19:00:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:00:27
Data point term sent to Coder	System	19 Aug 2020 19:00:10
User entered 'INSOMNIA'	(b) (4), (b) (6)	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 2004'		19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'		19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2004'	System	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2004'	System	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:59:15

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:41
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual disorders NEC, PT: Diplopia, LLT: Diplopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:35:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:35:10
Data point term sent to Coder	System	19 Aug 2020 19:00:12
User entered 'BILATERAL DIPLOPIA'	(b) (4), (b) (6)	19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 2012'		19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'		19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.		19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2012'	System	19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2012'	System	19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 18:59:37

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User closed query 'Per MM: Please confirm this event does not meet exclusion criteria #8 (Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy). If yes, please ensure a protocol deviation is captured (as appropriate) ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 05:01:05
Query 'Per MM: Please confirm this event does not meet exclusion criteria #8 (Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy). If yes, please ensure a protocol deviation is captured (as appropriate) ' answered with 'this does not meet exclusion criteria as it is stable' (Site from DM).	Steven Anderson (b) (4) (b) (4)	07 Oct 2020 16:03:40
User opened query 'Per MM: Please confirm this event does not meet exclusion criteria #8 (Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy). If yes, please ensure a protocol deviation is captured (as appropriate) ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:48:05
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Platelet disorders, HLT: Thrombocytopenias, PT: Immune thrombocytopenia, LLT: Idiopathic thrombocytopenic purpura - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 13:22:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 13:22:29
Data point term sent to Coder	System	19 Aug 2020 19:00:13
User entered 'IDIOPATHIC THROMBOCYTOPENIC PURPURA (STABLE)'	(b) (4), (b) (6)	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2010'	System	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2010'	System	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 19:00:06

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:02:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:02:25
Data point term sent to Coder	System	19 Aug 2020 19:01:14
User entered 'OSTEOPOROSIS'	(b) (4), (b) (6)	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 2008'	(b) (4), (b) (6)	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2008'	System	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2008'	System	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 19:00:29

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:41:50
User closed query 'Per MM, ESSENTIAL TREMORS is a symptom not a medical diagnosis, the etiology should be clarified if possible' (Site from DM).		16 Oct 2020 05:02:37
User closed query 'Per DM CLR: Please specify the locations of Tremor (i.e. hands, arms, head, voice, chin, trunk and legs). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		16 Oct 2020 05:02:27
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:17:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 12:17:29
Data point term sent to Coder	System	08 Oct 2020 20:51:39
Query 'Per DM CLR: Please specify the locations of Tremor (i.e. hands, arms, head, voice, chin, trunk and legs). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'location of tremors has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:51:08
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:50:54
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:50:54
User entered 'ESSENTIAL TREMORS in bilateral hands and neck' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:50:54

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Query 'Per MM, ESSENTIAL TREMORS is a symptom not a medical diagnosis, the etiology should be clarified if possible' answered with 'per sub I and PI this is a diagnosis for this subject. terminology will not be updated' (Site from DM).	Steven Anderson (b) (4)	08 Oct 2020 17:30:15
User opened query 'Per DM CLR: Please specify the locations of Tremor (i.e. hands, arms, head, voice, chin, trunk and legs). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 16:22:25
User opened query 'Per MM, ESSENTIAL TREMORS is a symptom not a medical diagnosis, the etiology should be clarified if possible' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:48:23
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:02:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 19:02:26
Data point term sent to Coder	System	19 Aug 2020 19:01:14
User entered 'ESSENTIAL TREMORS'	(b) (4), (b) (6)	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'UN UNK 2014'	(b) (4), (b) (6)	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:11:41
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2014'	System	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2014'	System	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	19 Aug 2020 19:00:50

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 20:07:09
User closed query 'Thank you - please correct spelling to cholecystitis as discussed' (Site from CRA).		01 Dec 2020 20:07:07
User coded data point as SOC: Hepatobiliary disorders, HLT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 14:52:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 14:52:01
Data point term sent to Coder	System	19 Nov 2020 14:50:40
Query 'Thank you - please correct spelling to cholecystitis as discussed' answered with 'UPDATED SPELLING OF MEDICAL CONDITION (MEF-19-NOV-2020)' (Site from CRA).	Melissa Fuson (b) (4)	19 Nov 2020 14:50:31
User entered 'CHOLECYSTITIS' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 14:49:56
User opened query 'Thank you - please correct spelling to cholecystitis as discussed' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:45:44
Query 'Thank you - please correct spelling to cholecystitis' canceled (Site from CRA).		18 Nov 2020 17:45:31
User opened query 'Thank you - please correct spelling to cholecystitis' (Site from CRA).		18 Nov 2020 17:45:07
User closed query 'Please clarify condition and update as appropriate' (Site from CRA).		18 Nov 2020 17:45:07
Data point term sent to Coder	System	18 Nov 2020 17:08:04
Query 'Please clarify condition and update as appropriate' answered with 'CORRECTED SPELLING OF CONDITION AND PLEASE NOTE CONDITION ENDED IN 2014' (Site from CRA).	Melissa Fuson (b) (4)	18 Nov 2020 17:08:03
Coding entries removed.	Melissa Fuson (b) (4)	18 Nov 2020 17:07:14
User entered 'CHOLOECYSLITIES' reason for change: Data Entry Error	Melissa Fuson (b) (4)	18 Nov 2020 17:07:14

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Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Please clarify condition and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 15:43:17
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 18:36:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 18:36:38
Data point term sent to Coder	System	24 Sep 2020 12:55:08
User entered 'CHOLEYSLITOS'	Melissa Fuson (b) (4)	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:45:14
User entered 'UN UNK 2014'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:45:15
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:45:17
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:45:18
User entered 'UN UNK 2014'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:45:20
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2014'	System	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2014'	System	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2014'	System	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2014'	System	24 Sep 2020 12:54:34

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:29
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)	24 Sep 2020 18:50:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:50:34
Data point term sent to Coder	System	24 Sep 2020 18:09:29
User entered 'Alergic to Penicillin'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:31
User entered 'un UNK 1966' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Sep 2020 18:10:41
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:33
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	System	24 Sep 2020 18:11:00
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Sep 2020 18:11:00
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System).	(b) (4)	24 Sep 2020 18:10:41
User entered '1'	Melissa Fuson (b) (4)	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:35
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:36
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:39
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1966'	System	24 Sep 2020 18:10:41
User entered empty.	System	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1966'	System	24 Sep 2020 18:10:41
User entered empty.	System	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	24 Sep 2020 18:09:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:46
User coded data point as SOC: Immune system disorders, HLT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:11:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 18:11:51
Data point term sent to Coder	System	24 Sep 2020 18:10:30
User entered 'Alergic to Sulfa Drugs'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:49
User entered 'un UNK 1966'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:52
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:54
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:56
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:43:58
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1966'	System	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1966'	System	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	24 Sep 2020 18:10:17

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 18:23:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 18:23:53
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:44:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 18:49:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Sep 2020 18:49:38
Data point term sent to Coder	System	24 Sep 2020 18:12:32
User entered 'Alergic to Naproxen'	Melissa Fuson (b) (4)	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:10
User entered 'un UNK 2010'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:13
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:15
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:19
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2010'	System	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2010'	System	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	24 Sep 2020 18:11:42

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:28
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:14:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:14:53
Data point term sent to Coder	System	07 Oct 2020 16:12:38
User entered 'Headaches/migraines'	Steven Anderson (b) (4) (b) (4)	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:30
User entered 'UN UNK 2000' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:35:49
User entered 'un UNK 2010'	Steven Anderson (b) (4) (b) (4)	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:32
User entered '0'	Steven Anderson (b) (4)	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:34
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:36
User entered empty.	Steven Anderson (b) (4)	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:38
User entered '0'	Steven Anderson (b) (4)	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2000'	System	20 Oct 2020 13:35:49
User entered 'Jan 2010'	System	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2000'	System	20 Oct 2020 13:35:49
User entered '2010'	System	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	07 Oct 2020 16:12:33

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:50
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:38:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:38:50
Data point term sent to Coder	System	08 Oct 2020 17:07:15
User entered 'Overweight'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:52
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	08 Oct 2020 17:07:19
User entered 'un Jan 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 17:07:19
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	08 Oct 2020 17:07:00
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:54
User entered '0'	Steven Anderson (b) (4)	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:56
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:58
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:45:01
User entered '0'	Steven Anderson (b) (4)	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2020'	System	08 Oct 2020 17:07:19
User entered empty.	System	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2020'	System	08 Oct 2020 17:07:19
User entered empty.	System	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	08 Oct 2020 17:07:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:46:51
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).		09 Nov 2020 13:48:12
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'no known underlying medical condition which led to this surgery ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	27 Oct 2020 13:04:49
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 12:48:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:38:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:38:29
Data point term sent to Coder	System	12 Oct 2020 17:37:42
User entered 'HYSTERECTOMY'	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User closed query 'Please confirm year and update as appropriate' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:47:19
DataPoint Verified.		18 Nov 2020 17:47:16
Query 'Please confirm year and update as appropriate' answered with 'CONFIRMED WITH SOURCE OF MEDICAL HYSTORY THE YEAR IS 2004' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 17:12:12
User opened query 'Please confirm year and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 15:46:49
User entered 'UN UNK 2004'	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:15
User entered '0'	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:17
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:47:22
User entered 'UN UNK 2004'	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:47:19
User entered '0'	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2004'	System	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2004'	System	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2004'	System	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2004'	System	12 Oct 2020 17:37:00

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:58:13
User closed query 'please update to cholecystitis per source' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:58:11
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:35:52
Query 'please update to cholecystitis per source' answered with 'this has been updated to the correct term' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:35:35
Data point term sent to Coder	System	16 Mar 2021 14:35:13
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:35:01
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:35:01
User entered 'Cholecystitis' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:35:01
User opened query 'please update to cholecystitis per source' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 16:26:42
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 04:59:12
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)	18 Nov 2020 17:14:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 17:14:47
Data point term sent to Coder	System	18 Nov 2020 17:14:09
User entered 'CHOLECYSTECTOMY'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:27:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2014'	Melissa Fuson (b) (4)	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:27:15
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:27:19
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'No (N)'	Melissa Fuson (b) (4)	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:27:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2014'	Melissa Fuson (b) (4)	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:27:26
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2014'	System	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2014'	System	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2014'	System	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (17)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2014'	System	18 Nov 2020 17:13:27

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:27:58
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 07:28:33
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'ADDED TMJ DISORDER TO MEDICAL HISTORY' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:13:29
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. '(Site from DM).	(b) (4), (b) (6)	14 Jan 2021 02:01:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Temporomandibular joint surgery, LLT: Temporomandibular joint surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:37:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:37:59
Data point term sent to Coder	System	18 Nov 2020 17:15:12
User entered 'TMJ SURGERY'	Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:28:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 1988'	Melissa Fuson (b) (4)	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:28:05
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:28:07
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'No (N)'	Melissa Fuson (b) (4)	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:28:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 1988'	Melissa Fuson (b) (4)	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:28:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1988'	System	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1988'	System	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1988'	System	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (18)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1988'	System	18 Nov 2020 17:15:03

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Shoulder operation, LLT: Shoulder operation - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:53:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:53:25
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
Data point term sent to Coder	System	16 Mar 2021 14:41:18
Coding entries removed.	Steven Anderson (b) (4)	16 Mar 2021 14:41:02
Signature has been broken.	Steven Anderson (b) (4)	16 Mar 2021 14:41:02
User entered 'RIGHT SHOULDER SURGERy (BURSITIS)' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Mar 2021 14:41:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Shoulder bursitis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 03:41:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 03:41:07
Data point term sent to Coder	System	18 Nov 2020 17:17:13
User entered 'RIGHT SHOULDER SURGER (BURSITIS)'	Melissa Fuson (b) (4)	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2007'	Melissa Fuson (b) (4)	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2007'	Melissa Fuson (b) (4)	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2007'	System	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2007'	System	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2007'	System	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (19)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2007'	System	18 Nov 2020 17:16:25

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Benign tumour excision, LLT: Benign tumor excision - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 14:59:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 14:59:57
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:04
User closed query 'please correct or to on' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:59:01
Data point term sent to Coder	System	16 Mar 2021 14:38:16
Query 'please correct or to on' answered with 'this has been corrected' (Site from CRA).	Steven Anderson (b) (4)	16 Mar 2021 14:37:32
Coding entries removed.	Steven Anderson (b) (4)	16 Mar 2021 14:37:24
Signature has been broken.	Steven Anderson (b) (4)	16 Mar 2021 14:37:24
User entered 'RIGHT BENIGN TUMOR (On CAROTID) REMOVAL' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Mar 2021 14:37:24
User opened query 'please correct or to on' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 16:29:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Benign tumour excision, LLT: Benign tumor excision - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 12:49:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 12:49:58
Data point term sent to Coder	System	10 Dec 2020 14:32:29
User closed query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) Benign neoplasm of carotid body 2) benign neoplasm removal (with location) etc.' (Site from System).	System	10 Dec 2020 14:32:27

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) Benign neoplasm of carotid body 2) benign neoplasm removal (with location) etc.' answered with 'UPDATED PER DM CODING AND SEPARATED CONDITIONS' (Site from System).	Melissa Fuson (b) (4)	10 Dec 2020 14:32:27
User opened query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) Benign neoplasm of carotid body 2) benign neoplasm removal (with location) etc.' (Site from System).	Coder Import (b) (4)	19 Nov 2020 08:01:55
Data point term sent to Coder	System	18 Nov 2020 17:18:16
User entered 'RIGHT BENIGN TUMOR (OR CAROTID) REMOVAL'	Melissa Fuson (b) (4)	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:29:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2010'	Melissa Fuson (b) (4)	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:29:39
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:29:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:29:45
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2010'	Melissa Fuson (b) (4)	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:29:47
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2010'	System	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2010'	System	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2010'	System	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (20)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2010'	System	18 Nov 2020 17:18:01

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
User closed query 'please correct spelling - should be Benign neoplasm on Carotid (right)' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:00:04
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Endocrine neoplasms benign NEC, PT: Paraganglion neoplasm benign, LLT: Benign neoplasm of carotid body - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:48:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:48:40
Data point term sent to Coder	System	16 Mar 2021 14:38:15
Query 'please correct spelling - should be Benign neoplasm on Carotid (right)' answered with 'this has been corrected' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:38:06
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:37:52
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:37:52
User entered 'Benign neoplasm on Carotid (right)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:37:52
User opened query 'please correct spelling - should be Benign neoplasm on Carotid (right)' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 16:31:04
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 04:59:12
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms benign, HLT: Endocrine neoplasms benign NEC, PT: Paraganglion neoplasm benign, LLT: Benign neoplasm of carotid body - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 21:15:56
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 21:15:56
Data point term sent to Coder	System	10 Dec 2020 14:34:30

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
User entered 'BENIGN NEOPLASM OF AROTID (RIGHT)'	Melissa Fuson (b) (4)	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:07
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2010'	Melissa Fuson (b) (4)	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:09
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:11
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:14
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 2010'	Melissa Fuson (b) (4)	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:17
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2010'	System	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2010'	System	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2010'	System	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (21)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2010'	System	10 Dec 2020 14:33:54

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Temporomandibular joint syndrome, LLT: Temporomandibular joint disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:15:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:15:06
Data point term sent to Coder	System	21 Jan 2021 15:14:51
User entered 'TMJ DISORDER'	Melissa Fuson (b) (4)	21 Jan 2021 15:13:56
	(b) (4)	

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:31
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 1988'	Melissa Fuson (b) (4)	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:38
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'No (N)'	Melissa Fuson (b) (4)	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'UN UNK 1988'	Melissa Fuson (b) (4)	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:31:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	(b) (4) Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1988'	System	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1988'	System	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 1988'	System	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (23)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '1988'	System	21 Jan 2021 15:13:56

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:32:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:19:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 15:19:01
Data point term sent to Coder	System	21 Jan 2021 15:17:53
User entered 'POST -MENOPAUSAL'	Melissa Fuson (b) (4)	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
User closed query 'per source, start UN UNK 2004? Please confirm and update accordingly' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:00:44
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
Query 'per source, start UN UNK 2004? Please confirm and update accordingly' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:38:46
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:38:35
User entered 'un UNK 2004' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:38:35
User opened query 'per source, start UN UNK 2004? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	13 Mar 2021 16:32:50
User signature succeeded.	Richard Powell (b) (4) (b) (4)	13 Feb 2021 04:59:12
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:59:36
User closed query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). Signature has been broken.	System	16 Mar 2021 14:38:53
	Steven Anderson (b) (4)	16 Mar 2021 14:38:53
User entered '0' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	16 Mar 2021 14:38:53
User opened query 'Start date completely unknown is checked, however Start date has been provided. Please correct.' (Site from System). User signature succeeded.	(b) (4) Richard Powell (b) (4)	16 Mar 2021 14:38:35 13 Feb 2021 04:59:12
User entered '1'	(b) (4) Melissa Fuson (b) (4)	21 Jan 2021 15:17:36
	(b) (4)	

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:32:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:32:56
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered empty.	Melissa Fuson (b) (4)	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:32:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	Melissa Fuson (b) (4)	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2004'	System	16 Mar 2021 14:38:35
User entered empty.	System	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2004'	System	16 Mar 2021 14:38:35
User entered empty.	System	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (24)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered empty.	System	21 Jan 2021 15:17:36

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:59:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Bursal disorders, PT: Bursitis, LLT: Bursitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:42:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:42:53
Data point term sent to Coder	System	16 Mar 2021 14:42:29
User entered 'Bursitis'	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User entered 'un UNK 2007'	Steven Anderson (b) (4)	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User entered 'No (N)'	Steven Anderson (b) (4)	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User entered 'un UNK 2007'	Steven Anderson (b) (4)	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 15:59:36
User entered '0'	Steven Anderson (b) (4)	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2007'	System	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2007'	System	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'Jan 2007'	System	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Medical History (25)

Generated On: 11 Aug 2021 22:33:31

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '2007'	System	16 Mar 2021 14:41:35

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered 'Yes (Y)'		19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Aug 2020 19:26:49
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	19 Aug 2020 19:25:04
User entered '13 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '09:29'	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered '13 Aug 2020 09:29'	System	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '166.4' cm	(b) (4), (b) (6)	19 Aug 2020 19:25:04
DataPoint set to visible.	System	14 Aug 2020 17:00:44

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '85.4' kg	(b) (4), (b) (6)	19 Aug 2020 19:25:04
DataPoint set to visible.	System	14 Aug 2020 17:00:44

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
Amendment Manager: User entered '30.84262'	System	16 Sep 2020 23:54:51
User entered '30.8'	System	19 Aug 2020 19:25:04
DataPoint set to visible.	System	14 Aug 2020 17:00:44

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'kg/m2'	System	19 Aug 2020 19:25:04
DataPoint set to visible.	System	14 Aug 2020 17:00:44

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '36.1' C		19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '48'	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'bpm'	System	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '12'	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'breaths/min'	System	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '118'	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'mmHg'	System	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:12:37
User entered '72'	(b) (4), (b) (6)	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User entered 'mmHg'	System	19 Aug 2020 19:25:04

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29

US3412224

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29

US3412224

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:27:20

US3412224

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:42:01
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 13:43:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 13:39:26
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:00
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	19 Aug 2020 19:27:20
User entered '13 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:27:20

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:15
User entered '13 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:15
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 04:59:45
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'VERIFIED AND UPDATED MEDICAL HISTORY WITH HYSTERECTOMY IN 2004' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	12 Oct 2020 17:37:29
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:38:30
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:15
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	19 Aug 2020 19:22:06
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	19 Aug 2020 19:21:46
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	19 Aug 2020 19:21:46

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	19 Aug 2020 19:21:46
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 19:21:46
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	19 Aug 2020 19:21:34
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	19 Aug 2020 19:21:34
User entered 'Partner medically sterile (PARTNER STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 19:21:34
User entered 'Post-menopausal (POST-MENOPAUSAL)'		19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:15
User closed query 'Partner medically sterile or Other has been entered, however specify is missing. Please provide.' (Site from System).	System	19 Aug 2020 19:21:46
User opened query 'Partner medically sterile or Other has been entered, however specify is missing. Please provide.' (Site from System).		19 Aug 2020 19:21:34
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:15
User entered 'UN UNK 2004' reason for change:		19 Aug 2020 19:21:34
Data Entry Error		
User entered empty.		19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:15
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:15
User entered empty; reason for change Data Entry Error		19 Aug 2020 19:22:06
User entered 'UN UNK 2004'		19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:33:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:15
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:02:34

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered 'l'	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:33:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:41:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:13:47
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:20:32

US3412224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:14:13
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:59

US3412224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:14:13
User entered '14 Aug 2020'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:59

US3412224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:14:13
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:00:59

US3412224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'VISIT1'	System	14 Aug 2020 17:00:59

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:50:22

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:06:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:06:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:50:22
User entered '104289' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:50:22

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:50:22

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:01:10

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

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)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:01:10

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:01:10

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:01:10

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:15:11
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:01:10

US3412224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:33:31

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:45
User entered 'No (N)'	Melissa Fuson (b) (4)	24 Sep 2020 12:58:03
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:57:32

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '167' cm		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '84.8' kg	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '167' cm	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '84.8' kg	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User accepted default value 'Pre-Dose (PREDOSE)'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '14 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '12:11'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '14 Aug 2020 12:11'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '36.6' C		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered 'Oral (Oral)'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered empty.		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '68'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'bpm'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '16'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'breaths/min'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '116'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '74'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '167' cm	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '84.8' kg	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User accepted default value 'Post-Dose (POSTDOSE)'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '14 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:28:45
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 19:34:13
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 19:34:06
User entered '13:31'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '14 Aug 2020 13:31'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
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) (4), (b) (6)	29 Sep 2020 12:44:15
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 'within range' (Site from System).	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 18:03:41
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	16 Sep 2020 23:54:51
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '96.3' F		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered 'Oral (Oral)'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered empty.		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '54'		19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'bpm'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '14'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'breaths/min'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '108'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:33
User entered '72'	(b) (4), (b) (6)	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	19 Aug 2020 19:34:06

US3412224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:34:26

US3412224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:18:50
User entered '14 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:34:26

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:10
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:10
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:10
User entered empty.	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:10
User entered '14 Aug 2020'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:10
User entered '13:00'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '14 Aug 2020 13:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:10
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4) (b) (4)	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
DataPoint Verified.		26 Aug 2020 15:19:10
User entered 'ONCE'	System	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 17:02:09

US3412224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:25
User entered 'Yes (Y)'		19 Aug 2020 19:34:59

US3412224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:27
User entered '14 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:34:59

US3412224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:29
User entered '12:36'	(b) (4), (b) (6)	19 Aug 2020 19:34:59

US3412224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '14 Aug 2020 12:36'	System	19 Aug 2020 19:34:59

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:39
User entered '14 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:39
User entered '12:41'	(b) (4), (b) (6)	19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered '14 Aug 2020 12:41'	System	19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:39
User entered 'No (N)'		19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:19:39
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered empty.	System	19 Aug 2020 19:35:15

US3412224

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
User closed query 'Please enter Not done on Safety Call Day 8 CRF' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:23:37
Query 'Please enter Not done on Safety Call Day 8 CRF' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	08 Oct 2020 17:11:58
User opened query 'Please enter Not done on Safety Call Day 8 CRF' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:19:26
DataPoint Verified.		26 Aug 2020 15:19:53
User entered 'Yes (Y)'		19 Aug 2020 19:35:22

US3412224

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	19 Aug 2020 19:35:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:36:39', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '196e047f-0209-4284-9b00-545114ba93ca' User entered 'Yes (Y)'	System	14 Aug 2020 17:37:22
	System	14 Aug 2020 17:37:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:36:49', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '196e047f-0209-4284-9b00-545114ba93ca' User entered '96.3'	System	14 Aug 2020 17:37:22
	System	14 Aug 2020 17:37:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:36:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '196e047f-0209-4284-9b00-545114ba93ca'	System	14 Aug 2020 17:37:22
User entered 'No (N)'	System	14 Aug 2020 17:37:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:37:18', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '196e047f-0209-4284-9b00-545114ba93ca' User entered '14 Aug 2020 13:37'	System	14 Aug 2020 17:37:22
	System	14 Aug 2020 17:37:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 13:20'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 15:50'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:37:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51cf0ee8-4f81-4f75-8b6b-166d14055cef' User entered 'Yes (Y)'	System	14 Aug 2020 23:37:44
	System	14 Aug 2020 23:37:44

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:37:29', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51cf0ee8-4f81-4f75-8b6b-166d14055cef' User entered '96.3'	System	14 Aug 2020 23:37:44
	System	14 Aug 2020 23:37:44

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:37:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51cf0ee8-4f81-4f75-8b6b-166d14055cef'	System	14 Aug 2020 23:37:44
User entered 'No (N)'	System	14 Aug 2020 23:37:44

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:37:41', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51cf0ee8-4f81-4f75-8b6b-166d14055cef' User entered '14 Aug 2020 19:37'	System	14 Aug 2020 23:37:44
	System	14 Aug 2020 23:37:44

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 16:45'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 2'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:36:43', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e1536661-81a0-4184-a866-8e059182b20a' User entered 'Yes (Y)'	System	15 Aug 2020 23:37:19
	System	15 Aug 2020 23:37:19

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:37:02', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e1536661-81a0-4184-a866-8e059182b20a' User entered '96.9'	System	15 Aug 2020 23:37:19
	System	15 Aug 2020 23:37:19

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:37:11', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e1536661-81a0-4184-a866-8e059182b20a'	System	15 Aug 2020 23:37:19
User entered 'No (N)'	System	15 Aug 2020 23:37:19

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:37:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e1536661-81a0-4184-a866-8e059182b20a' User entered '15 Aug 2020 19:37'	System	15 Aug 2020 23:37:19
	System	15 Aug 2020 23:37:19

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 3'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:03:05', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '6ce0f542-df69-4f6d-955e-469b547a3d6b'	System	17 Aug 2020 00:03:22
User entered 'Yes (Y)'	System	17 Aug 2020 00:03:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:03:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '6ce0f542-df69-4f6d-955e-469b547a3d6b' User entered '96.7'	System	17 Aug 2020 00:03:22
	System	17 Aug 2020 00:03:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:03:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '6ce0f542-df69-4f6d-955e-469b547a3d6b'	System	17 Aug 2020 00:03:22
User entered 'No (N)'	System	17 Aug 2020 00:03:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:03:21', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '6ce0f542-df69-4f6d-955e-469b547a3d6b' User entered '16 Aug 2020 20:03'	System	17 Aug 2020 00:03:22
	System	17 Aug 2020 00:03:22

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 4'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:47:54', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '75802f48-ed86-414e-a8bd-d22ba532d1bb' User entered 'Yes (Y)'	System	18 Aug 2020 00:48:27
	System	18 Aug 2020 00:48:27

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:47:59', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '75802f48-ed86-414e-a8bd-d22ba532d1bb' User entered '96.6'	System	18 Aug 2020 00:48:27
	System	18 Aug 2020 00:48:27

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:48:13', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '75802f48-ed86-414e-a8bd-d22ba532d1bb' User entered 'No (N)'	System	18 Aug 2020 00:48:27
	System	18 Aug 2020 00:48:27

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:48:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '75802f48-ed86-414e-a8bd-d22ba532d1bb' User entered '17 Aug 2020 20:48'	System	18 Aug 2020 00:48:27
	System	18 Aug 2020 00:48:27

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 5'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:12:07', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cdc88063-0843-43e6-aa32-cc2d48fbef1f' User entered 'Yes (Y)'	System	18 Aug 2020 22:13:21
	System	18 Aug 2020 22:13:21

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:12:18', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cdc88063-0843-43e6-aa32-cc2d48fbef1f' User entered '96.4'	System	18 Aug 2020 22:13:21
	System	18 Aug 2020 22:13:21

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:12:56', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cdc88063-0843-43e6-aa32-cc2d48fbef1f'	System	18 Aug 2020 22:13:21
User entered 'No (N)'	System	18 Aug 2020 22:13:21

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:13:19', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cdc88063-0843-43e6-aa32-cc2d48fbef1f' User entered '18 Aug 2020 18:13'	System	18 Aug 2020 22:13:21
	System	18 Aug 2020 22:13:21

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 6'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:25:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c8579592-7043-4c3b-b689-e671d7c1a40f'	System	20 Aug 2020 00:26:16
User entered 'Yes (Y)'	System	20 Aug 2020 00:26:16

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:26:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c8579592-7043-4c3b-b689-e671d7c1a40f'	System	20 Aug 2020 00:26:16
User entered '96.0'	System	20 Aug 2020 00:26:16

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:26:05', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c8579592-7043-4c3b-b689-e671d7c1a40f'	System	20 Aug 2020 00:26:16
User entered 'No (N)'	System	20 Aug 2020 00:26:16

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:26:11', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c8579592-7043-4c3b-b689-e671d7c1a40f'	System	20 Aug 2020 00:26:16
User entered '19 Aug 2020 20:26'	System	20 Aug 2020 00:26:16

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 7'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:19:49', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f9a03c87-a932-4504-812c-442115ba557a' User entered 'Yes (Y)'	System	21 Aug 2020 00:20:18
	System	21 Aug 2020 00:20:18

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:19:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f9a03c87-a932-4504-812c-442115ba557a' User entered '96.2'	System	21 Aug 2020 00:20:18
	System	21 Aug 2020 00:20:18

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:20:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f9a03c87-a932-4504-812c-442115ba557a'	System	21 Aug 2020 00:20:18
User entered 'No (N)'	System	21 Aug 2020 00:20:18

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:20:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f9a03c87-a932-4504-812c-442115ba557a' User entered '20 Aug 2020 20:20'	System	21 Aug 2020 00:20:18
	System	21 Aug 2020 00:20:18

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:39:24', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cfd8ad75-b05b-4ff1-b051-ca393ca477ea'	System	14 Aug 2020 17:40:03
User entered 'None (1)'	System	14 Aug 2020 17:40:03

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:39:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cfd8ad75-b05b-4ff1-b051-ca393ca477ea' User entered 'Yes (Y)'	System	14 Aug 2020 17:40:03
	System	14 Aug 2020 17:40:03

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:39:41', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cfd8ad75-b05b-4ff1-b051-ca393ca477ea' User entered '5'	System	14 Aug 2020 17:40:03
	System	14 Aug 2020 17:40:03

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:39:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cfd8ad75-b05b-4ff1-b051-ca393ca477ea' User entered 'No (N)'	System	14 Aug 2020 17:40:03
	System	14 Aug 2020 17:40:03

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:39:54', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cfd8ad75-b05b-4ff1-b051-ca393ca477ea' User entered 'None (1)'	System	14 Aug 2020 17:40:03
	System	14 Aug 2020 17:40:03

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:40:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cfd8ad75-b05b-4ff1-b051-ca393ca477ea'	System	14 Aug 2020 17:40:03
User entered '14 Aug 2020 13:40'	System	14 Aug 2020 17:40:03

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 13:20'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 15:50'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:37:53', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a68a5e60-7176-4b87-aa2c-46f02d810bfc' User entered 'None (1)'	System	14 Aug 2020 23:41:16
	System	14 Aug 2020 23:41:16

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:40:07', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a68a5e60-7176-4b87-aa2c-46f02d810bfc' User entered 'No (N)'	System	14 Aug 2020 23:41:16
	System	14 Aug 2020 23:41:16

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:40:14', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a68a5e60-7176-4b87-aa2c-46f02d810bfc' User entered 'No (N)'	System	14 Aug 2020 23:41:16
	System	14 Aug 2020 23:41:16

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:41:06', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a68a5e60-7176-4b87-aa2c-46f02d810bfc' User entered 'None (1)'	System	14 Aug 2020 23:41:16
	System	14 Aug 2020 23:41:16

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:41:14', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a68a5e60-7176-4b87-aa2c-46f02d810bfc' User entered '14 Aug 2020 19:41'	System	14 Aug 2020 23:41:16
	System	14 Aug 2020 23:41:16

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 16:45'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 2'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:38:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5b560903-f84b-421b-9538-607af3ac8d03' User entered 'None (1)'	System	15 Aug 2020 23:39:42
	System	15 Aug 2020 23:39:42

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:38:31', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5b560903-f84b-421b-9538-607af3ac8d03'	System	15 Aug 2020 23:39:42
User entered 'No (N)'	System	15 Aug 2020 23:39:42

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:38:36', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5b560903-f84b-421b-9538-607af3ac8d03'	System	15 Aug 2020 23:39:42
User entered 'No (N)'	System	15 Aug 2020 23:39:42

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:39:37', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5b560903-f84b-421b-9538-607af3ac8d03' User entered 'None (1)'	System	15 Aug 2020 23:39:42
	System	15 Aug 2020 23:39:42

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:39:41', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5b560903-f84b-421b-9538-607af3ac8d03' User entered '15 Aug 2020 19:39'	System	15 Aug 2020 23:39:42
	System	15 Aug 2020 23:39:42

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 3'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:03:39', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3d1ef116-7c65-4126-b83b-8556cb06c825' User entered 'None (1)'	System	17 Aug 2020 00:06:27
	System	17 Aug 2020 00:06:27

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:04:04', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3d1ef116-7c65-4126-b83b-8556cb06c825'	System	17 Aug 2020 00:06:27
User entered 'No (N)'	System	17 Aug 2020 00:06:27

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:04:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3d1ef116-7c65-4126-b83b-8556cb06c825'	System	17 Aug 2020 00:06:27
User entered 'No (N)'	System	17 Aug 2020 00:06:27

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:06:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3d1ef116-7c65-4126-b83b-8556cb06c825' User entered 'None (1)'	System	17 Aug 2020 00:06:27
	System	17 Aug 2020 00:06:27

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:06:23', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3d1ef116-7c65-4126-b83b-8556cb06c825'	System	17 Aug 2020 00:06:27
User entered '16 Aug 2020 20:06'	System	17 Aug 2020 00:06:27

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 4'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:48:57', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '471ad160-cc55-4ccf-8405-e6842289a88a' User entered 'None (1)'	System	18 Aug 2020 00:50:58
	System	18 Aug 2020 00:50:58

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:49:02', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '471ad160-cc55-4ccf-8405-e6842289a88a' User entered 'No (N)'	System	18 Aug 2020 00:50:58
	System	18 Aug 2020 00:50:58

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:49:07', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '471ad160-cc55-4ccf-8405-e6842289a88a' User entered 'No (N)'	System	18 Aug 2020 00:50:58
	System	18 Aug 2020 00:50:58

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:50:45', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '471ad160-cc55-4ccf-8405-e6842289a88a' User entered 'None (1)'	System	18 Aug 2020 00:50:58
	System	18 Aug 2020 00:50:58

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:50:56', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '471ad160-cc55-4ccf-8405-e6842289a88a' User entered '17 Aug 2020 20:50'	System	18 Aug 2020 00:50:58
	System	18 Aug 2020 00:50:58

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 5'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:13:59', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4892c6e7-522f-4a15-a047-0a51d511a4fc' User entered 'None (1)'	System	18 Aug 2020 22:15:24
	System	18 Aug 2020 22:15:24

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:14:04', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4892c6e7-522f-4a15-a047-0a51d511a4fc' User entered 'No (N)'	System	18 Aug 2020 22:15:24
	System	18 Aug 2020 22:15:24

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:14:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4892c6e7-522f-4a15-a047-0a51d511a4fc' User entered 'No (N)'	System	18 Aug 2020 22:15:24
	System	18 Aug 2020 22:15:24

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:15:19', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4892c6e7-522f-4a15-a047-0a51d511a4fc' User entered 'None (1)'	System	18 Aug 2020 22:15:24
	System	18 Aug 2020 22:15:24

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:15:23', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4892c6e7-522f-4a15-a047-0a51d511a4fc' User entered '18 Aug 2020 18:15'	System	18 Aug 2020 22:15:24
	System	18 Aug 2020 22:15:24

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 6'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:27:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4db7edb5-3456-4b8a-97a9-0cd4eb51f1b5'	System	20 Aug 2020 00:28:45
User entered 'None (1)'	System	20 Aug 2020 00:28:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:27:06', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4db7edbe-3456-4b8a-97a9-0cd4eb51f1b5'	System	20 Aug 2020 00:28:45
User entered 'No (N)'	System	20 Aug 2020 00:28:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:27:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4db7edbe-3456-4b8a-97a9-0cd4eb51f1b5'	System	20 Aug 2020 00:28:45
User entered 'No (N)'	System	20 Aug 2020 00:28:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:28:28', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4db7edbe-3456-4b8a-97a9-0cd4eb51f1b5' User entered 'None (1)'	System	20 Aug 2020 00:28:45
	System	20 Aug 2020 00:28:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:28:43', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4db7edbe-3456-4b8a-97a9-0cd4eb51f1b5' User entered '19 Aug 2020 20:28'	System	20 Aug 2020 00:28:45
	System	20 Aug 2020 00:28:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 7'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:20:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '2bd54ea5-70ff-41da-8822-d2411ad27e06' User entered 'None (1)'	System	21 Aug 2020 00:21:45
	System	21 Aug 2020 00:21:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:21:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '2bd54ea5-70ff-41da-8822-d2411ad27e06'	System	21 Aug 2020 00:21:45
User entered 'No (N)'	System	21 Aug 2020 00:21:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:21:05', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '2bd54ea5-70ff-41da-8822-d2411ad27e06'	System	21 Aug 2020 00:21:45
User entered 'No (N)'	System	21 Aug 2020 00:21:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:21:29', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '2bd54ea5-70ff-41da-8822-d2411ad27e06' User entered 'None (1)'	System	21 Aug 2020 00:21:45
	System	21 Aug 2020 00:21:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:21:42', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '2bd54ea5-70ff-41da-8822-d2411ad27e06'	System	21 Aug 2020 00:21:45
User entered '20 Aug 2020 20:21'	System	21 Aug 2020 00:21:45

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:40:32', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e' User entered 'None (0)'	System	14 Aug 2020 17:41:19
	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:40:37', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e' User entered 'None (0)'	System	14 Aug 2020 17:41:19
	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:40:46', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e' User entered 'None (0)'	System	14 Aug 2020 17:41:19
	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:40:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e' User entered 'None (0)'	System	14 Aug 2020 17:41:19
	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:40:56', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e' User entered 'None (0)'	System	14 Aug 2020 17:41:19
	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:40:59', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e' User entered 'None (0)'	System	14 Aug 2020 17:41:19
	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:41:07', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e'	System	14 Aug 2020 17:41:19
User entered 'No (N)'	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T13:41:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e2da0b70-fdd6-4081-aef6-7b81bf69157e' User entered '14 Aug 2020 13:41'	System	14 Aug 2020 17:41:19
	System	14 Aug 2020 17:41:19

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 13:20'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 15:50'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:41:37', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered 'None (0)'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:42:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered 'None (0)'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:43:20', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered 'None (0)'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:43:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered 'None (0)'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:43:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered 'None (0)'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:43:39', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered 'None (0)'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:43:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered 'No (N)'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-14T19:43:58', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0fd2c94a-57b0-4054-b3e9-0922e8b5eabe' User entered '14 Aug 2020 19:43'	System	14 Aug 2020 23:44:03
	System	14 Aug 2020 23:44:03

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Aug 2020 16:45'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 2'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:39:51', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6' User entered 'None (0)'	System	15 Aug 2020 23:40:49
	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:40:44', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6' User entered 'None (0)'	System	15 Aug 2020 23:40:49
	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:40:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6' User entered 'None (0)'	System	15 Aug 2020 23:40:49
	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:40:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6' User entered 'None (0)'	System	15 Aug 2020 23:40:49
	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:40:21', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6' User entered 'None (0)'	System	15 Aug 2020 23:40:49
	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:40:24', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6' User entered 'None (0)'	System	15 Aug 2020 23:40:49
	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:40:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6'	System	15 Aug 2020 23:40:49
User entered 'No (N)'	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-15T19:40:47', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8f263b32-1b72-4cba-b5dc-05d781540be6' User entered '15 Aug 2020 19:40'	System	15 Aug 2020 23:40:49
	System	15 Aug 2020 23:40:49

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 3'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:06:28', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639' User entered 'None (0)'	System	17 Aug 2020 00:07:33
	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:06:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639'	System	17 Aug 2020 00:07:33
User entered 'None (0)'	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:06:47', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639'	System	17 Aug 2020 00:07:33
User entered 'None (0)'	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:07:04', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639'	System	17 Aug 2020 00:07:33
User entered 'None (0)'	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:07:07', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639' User entered 'None (0)'	System	17 Aug 2020 00:07:33
	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:07:18', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639' User entered 'None (0)'	System	17 Aug 2020 00:07:33
	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:07:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639'	System	17 Aug 2020 00:07:33
User entered 'No (N)'	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-16T20:07:31', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30e70d64-660e-4865-91ac-748cb24e2639'	System	17 Aug 2020 00:07:33
User entered '16 Aug 2020 20:07'	System	17 Aug 2020 00:07:33

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 4'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:51:02', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8' User entered 'None (0)'	System	18 Aug 2020 00:52:18
	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:51:11', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8'	System	18 Aug 2020 00:52:18
User entered 'None (0)'	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:51:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8' User entered 'None (0)'	System	18 Aug 2020 00:52:18
	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:51:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8' User entered 'None (0)'	System	18 Aug 2020 00:52:18
	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:51:37', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8'	System	18 Aug 2020 00:52:18
User entered 'None (0)'	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:51:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8' User entered 'None (0)'	System	18 Aug 2020 00:52:18
	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:52:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8'	System	18 Aug 2020 00:52:18
User entered 'No (N)'	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-17T20:52:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '64018dca-f182-4c39-a61a-88e48669b0d8' User entered '17 Aug 2020 20:52'	System	18 Aug 2020 00:52:18
	System	18 Aug 2020 00:52:18

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 5'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:15:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered 'None (0)'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:16:09', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered 'None (0)'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:16:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered 'None (0)'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:16:38', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered 'None (0)'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:16:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered 'None (0)'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:16:56', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered 'None (0)'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:17:07', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered 'Yes (Y)'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-18T18:17:13', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'fea9c3a9-e9e5-4cee-a525-b6e8a9c5a7ba' User entered '18 Aug 2020 18:17'	System	18 Aug 2020 22:17:16
	System	18 Aug 2020 22:17:16

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 6'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:28:51', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b' User entered 'None (0)'	System	20 Aug 2020 00:29:58
	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:29:09', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b' User entered 'None (0)'	System	20 Aug 2020 00:29:58
	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:29:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b' User entered 'None (0)'	System	20 Aug 2020 00:29:58
	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:29:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b' User entered 'None (0)'	System	20 Aug 2020 00:29:58
	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:29:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b' User entered 'None (0)'	System	20 Aug 2020 00:29:58
	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:29:40', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b' User entered 'None (0)'	System	20 Aug 2020 00:29:58
	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:29:53', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b'	System	20 Aug 2020 00:29:58
User entered 'No (N)'	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-19T20:29:56', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '9db58727-a8e9-433d-ac6c-98f40ce9a08b' User entered '19 Aug 2020 20:29'	System	20 Aug 2020 00:29:58
	System	20 Aug 2020 00:29:58

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 7'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:02', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e'	System	21 Aug 2020 00:23:00
User entered 'No interference with activity (1)'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:22', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e' User entered 'None (0)'	System	21 Aug 2020 00:23:00
	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:25', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e' User entered 'None (0)'	System	21 Aug 2020 00:23:00
	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:30', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e' User entered 'None (0)'	System	21 Aug 2020 00:23:00
	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:32', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e' User entered 'None (0)'	System	21 Aug 2020 00:23:00
	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:36', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e' User entered 'None (0)'	System	21 Aug 2020 00:23:00
	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:54', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e'	System	21 Aug 2020 00:23:00
User entered 'No (N)'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-08-20T20:22:58', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '06f766f3-390b-4f45-b379-f2379c6fe27e' User entered '20 Aug 2020 20:22'	System	21 Aug 2020 00:23:00
	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	21 Aug 2020 00:23:00
User entered 'Day 8'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '21 Aug 2020 12:00'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	21 Aug 2020 00:23:00
User entered 'Day 9'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	21 Aug 2020 00:23:00
User entered 'Day 8'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '21 Aug 2020 12:00'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	21 Aug 2020 00:23:00
User entered 'Day 9'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 00:23:00

US3412224

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 00:23:00

US3412224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:29
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Sep 2020 18:03:43
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	29 Sep 2020 18:03:08
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	29 Sep 2020 18:03:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 18:03:08
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	29 Sep 2020 18:02:59
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:05:21

US3412224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:29
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 18:02:59
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 18:02:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 18:02:55
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Sep 2020 18:02:55
User entered 'UN ' (non-conformant).	(b) (4), (b) (6)	29 Sep 2020 18:02:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 13:06:43
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Sep 2020 13:06:43
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	24 Sep 2020 13:06:43
User entered 'UN Aug 2020' (non-conformant).	Melissa Fuson (b) (4)	24 Sep 2020 13:06:43
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) System	24 Sep 2020 13:05:21
User entered '28 Aug 2020'	Melissa Fuson (b) (4)	24 Sep 2020 13:05:21

US3412224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 18:03:43
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Sep 2020 13:07:15
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4)	24 Sep 2020 13:05:21

US3412224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	29 Sep 2020 18:03:43
User entered 'NO SAFETY CALL SHEET IN FOLDER' reason for change: Data Entry Error	Melissa Fuson (b) (4)	24 Sep 2020 13:07:15
User entered empty.	Melissa Fuson (b) (4)	24 Sep 2020 13:05:21

US3412224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:35
User entered 'Yes (Y)'		28 Aug 2020 13:03:33

US3412224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	28 Aug 2020 13:03:33

US3412224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
User closed query 'Subject reported infected index finger 17 Aug 2020 from bug bite and clindamycin 300 mg for 10 days - please update AE and Con Med CRFs' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:21:16
Query 'Subject reported infected index finger 17 Aug 2020 from bug bite and clindamycin 300 mg for 10 days - please update AE and Con Med CRFs' answered with 'UPDATED ALL' (Site from CRA). DataPoint Verified.	Melissa Fuson (b) (4) (b) (4) (b) (4), (b) (6)	24 Sep 2020 13:22:53 10 Sep 2020 20:14:23
User opened query 'Subject reported infected index finger 17 Aug 2020 from bug bite and clindamycin 300 mg for 10 days - please update AE and Con Med CRFs' (Site from CRA).	(b) (4), (b) (6)	10 Sep 2020 20:12:46
User entered 'Yes (Y)'		28 Aug 2020 15:06:27

US3412224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:14:23
User entered '28 Aug 2020'		28 Aug 2020 15:06:27

US3412224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:14:23
User entered 'Contact Made (CONTACT MADE)'		28 Aug 2020 15:06:27

US3412224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:14:23
User entered empty.		28 Aug 2020 15:06:27

US3412224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:29:20
User entered 'Yes (Y)'		28 Aug 2020 15:06:32

US3412224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	28 Aug 2020 15:06:32

US3412224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:29:46
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	04 Sep 2020 16:51:19

US3412224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:29:46
User entered '4 Sep 2020'	Mason Urban (b) (4) (b) (4)	04 Sep 2020 16:51:19

US3412224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:29:46
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	04 Sep 2020 16:51:19

US3412224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:29:46
User entered empty.	Mason Urban (b) (4) (b) (4)	04 Sep 2020 16:51:19

US3412224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 15:30:14
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Sep 2020 16:51:24

US3412224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	04 Sep 2020 16:51:24

US3412224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:30:35
User entered 'Yes (Y)'	Zachary Eardley (b) (4)	11 Sep 2020 13:43:24

US3412224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:30:35
User entered '11 Sep 2020'	Zachary Eardley (b) (4)	11 Sep 2020 13:43:24

US3412224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:30:35
User entered 'Clinic (Clinic)'	Zachary Eardley (b) (4)	11 Sep 2020 13:43:24

US3412224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'VISIT2'	System	11 Sep 2020 13:43:24

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User accepted default value 'Pre-Dose (PREDOSE)'	Melissa Fuson (b) (4)	24 Sep 2020 13:26:32
	(b) (4)	

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '11 Sep 2020'	Melissa Fuson (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '09:04'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '11 Sep 2020 09:04'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '36.5' C	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '52'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'bpm'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '14'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'breaths/min'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '128'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '72'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User accepted default value 'Post-Dose (POSTDOSE)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '11 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '10:25'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '11 Sep 2020 10:25'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
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)	29 Sep 2020 12:46:47
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 'TEMP WITHIN RANGE' (Site from System).	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:29:02
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	24 Sep 2020 13:26:32
User entered '95.6' F	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '58'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'bpm'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '16'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'breaths/min'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '125'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:31:24
User entered '80'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'mmHg'	System	24 Sep 2020 13:26:32

US3412224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:00:05
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:30:13

US3412224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:00:08
User entered '11 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:30:13

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:22
User entered 'Yes (Y)'	Zachary Eardley (b) (4)	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:22
User entered empty.	Zachary Eardley (b) (4)	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:22
User entered empty.	Zachary Eardley (b) (4)	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:22
User entered '11 Sep 2020'	Zachary Eardley (b) (4)	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:22
User entered '09:50'	Zachary Eardley (b) (4)	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '11 Sep 2020 09:50'	System	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:22
User entered 'Left Arm (LEFT ARM)'	Zachary Eardley (b) (4)	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
DataPoint Verified.		19 Oct 2020 16:01:22
User entered 'ONCE'	System	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 13:52:30

US3412224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:41
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:35

US3412224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:41
User entered '11 Sep 2020'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:35

US3412224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:41
User entered '09:20'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:35

US3412224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '11 Sep 2020 09:20'	System	24 Sep 2020 13:31:35

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:01:45
User entered '11 Sep 2020'	Melissa Fuson (b) (4)	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:45
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:45
User entered '09:18'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '11 Sep 2020 09:18'	System	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:45
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:01:45
User entered empty.	Melissa Fuson (b) (4)	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered empty.	System	24 Sep 2020 13:31:55

US3412224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:01:57
User entered 'Yes (Y)'		18 Sep 2020 16:55:41

US3412224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'I'	System	18 Sep 2020 16:55:41

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:27:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5e80fcf9-27dd-4e9a-9136-0e89964d7db1' User entered 'Yes (Y)'	System	11 Sep 2020 14:27:35
	System	11 Sep 2020 14:27:35

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:27:24', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5e80fcf9-27dd-4e9a-9136-0e89964d7db1' User entered '95.6'	System	11 Sep 2020 14:27:35
	System	11 Sep 2020 14:27:35

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:27:29', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5e80fcf9-27dd-4e9a-9136-0e89964d7db1' User entered 'No (N)'	System	11 Sep 2020 14:27:35
	System	11 Sep 2020 14:27:35

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:27:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '5e80fcf9-27dd-4e9a-9136-0e89964d7db1' User entered '11 Sep 2020 10:27'	System	11 Sep 2020 14:27:35
	System	11 Sep 2020 14:27:35

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 10:10'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 12:40'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:10:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '874f0edf-7210-4c5d-9b65-232adcf7a593'	System	12 Sep 2020 00:11:14
User entered 'Yes (Y)'	System	12 Sep 2020 00:11:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '874f0edf-7210-4c5d-9b65-232adcf7a593'	System	12 Sep 2020 00:11:14
User entered '97.9'	System	12 Sep 2020 00:11:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:05', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '874f0edf-7210-4c5d-9b65-232adcf7a593'	System	12 Sep 2020 00:11:14
User entered 'No (N)'	System	12 Sep 2020 00:11:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '874f0edf-7210-4c5d-9b65-232adcf7a593'	System	12 Sep 2020 00:11:14
User entered '11 Sep 2020 20:11'	System	12 Sep 2020 00:11:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 13:35'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 2'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:04:21', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '430b502e-f8e1-4470-80a8-6b852261a2b4' User entered 'Yes (Y)'	System	13 Sep 2020 00:04:39
	System	13 Sep 2020 00:04:39

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:04:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '430b502e-f8e1-4470-80a8-6b852261a2b4' User entered '97.4'	System	13 Sep 2020 00:04:39
	System	13 Sep 2020 00:04:39

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:04:30', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '430b502e-f8e1-4470-80a8-6b852261a2b4' User entered 'No (N)'	System	13 Sep 2020 00:04:39
	System	13 Sep 2020 00:04:39

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:04:36', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '430b502e-f8e1-4470-80a8-6b852261a2b4'	System	13 Sep 2020 00:04:39
User entered '12 Sep 2020 20:04'	System	13 Sep 2020 00:04:39

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 3'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:05:10', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '1a3bb9ab-d867-4b0d-a224-9a9de5e75920'	System	14 Sep 2020 00:07:37
User entered 'Yes (Y)'	System	14 Sep 2020 00:07:37

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:05:18', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '1a3bb9ab-d867-4b0d-a224-9a9de5e75920' User entered '96.8'	System	14 Sep 2020 00:07:37
	System	14 Sep 2020 00:07:37

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:05:23', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '1a3bb9ab-d867-4b0d-a224-9a9de5e75920' User entered 'No (N)'	System	14 Sep 2020 00:07:37
	System	14 Sep 2020 00:07:37

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:05:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '1a3bb9ab-d867-4b0d-a224-9a9de5e75920'	System	14 Sep 2020 00:07:37
User entered '13 Sep 2020 20:05'	System	14 Sep 2020 00:07:37

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 4'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:35:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '28ffca6-0f62-4b56-b7c0-a458c06b1032'	System	15 Sep 2020 10:36:14
User entered 'Yes (Y)'	System	15 Sep 2020 10:36:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:35:39', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '28ffca6-0f62-4b56-b7c0-a458c06b1032' User entered '97.5'	System	15 Sep 2020 10:36:14
	System	15 Sep 2020 10:36:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:35:46', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '28ffca6-0f62-4b56-b7c0-a458c06b1032'	System	15 Sep 2020 10:36:14
User entered 'No (N)'	System	15 Sep 2020 10:36:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:35:53', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '28ffca6-0f62-4b56-b7c0-a458c06b1032'	System	15 Sep 2020 10:36:14
User entered '15 Sep 2020 06:35'	System	15 Sep 2020 10:36:14

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 5'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:54:03', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '522df227-0a51-4477-834d-a44ccdaa5d1f' User entered 'Yes (Y)'	System	15 Sep 2020 23:54:19
	System	15 Sep 2020 23:54:19

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:54:08', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '522df227-0a51-4477-834d-a44ccdaa5d1f' User entered '96.4'	System	15 Sep 2020 23:54:19
	System	15 Sep 2020 23:54:19

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:54:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '522df227-0a51-4477-834d-a44ccdaa5d1f' User entered 'No (N)'	System	15 Sep 2020 23:54:19
	System	15 Sep 2020 23:54:19

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:54:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '522df227-0a51-4477-834d-a44ccdaa5d1f' User entered '15 Sep 2020 19:54'	System	15 Sep 2020 23:54:19
	System	15 Sep 2020 23:54:19

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 6'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:20:38', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a4f2ee7c-bfdf-465b-ae02-156e1679f548'	System	17 Sep 2020 00:20:57
User entered 'Yes (Y)'	System	17 Sep 2020 00:20:57

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:20:45', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a4f2ee7c-bfdf-465b-ae02-156e1679f548' User entered '97.9'	System	17 Sep 2020 00:20:57
	System	17 Sep 2020 00:20:57

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:20:50', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a4f2ee7c-bfdf-465b-ae02-156e1679f548'	System	17 Sep 2020 00:20:57
User entered 'No (N)'	System	17 Sep 2020 00:20:57

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:20:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a4f2ee7c-bfdf-465b-ae02-156e1679f548'	System	17 Sep 2020 00:20:57
User entered '16 Sep 2020 20:20'	System	17 Sep 2020 00:20:57

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 7'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T19:59:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f41dad0-9a5f-4574-a4fd-b8081fdac15a'	System	18 Sep 2020 00:00:12
User entered 'Yes (Y)'	System	18 Sep 2020 00:00:12

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f41dad0-9a5f-4574-a4fd-b8081fdac15a' User entered '96.0'	System	18 Sep 2020 00:00:12
	System	18 Sep 2020 00:00:12

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:04', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f41dad0-9a5f-4574-a4fd-b8081fdac15a'	System	18 Sep 2020 00:00:12
User entered 'No (N)'	System	18 Sep 2020 00:00:12

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:08', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f41dad0-9a5f-4574-a4fd-b8081fdac15a'	System	18 Sep 2020 00:00:12
User entered '17 Sep 2020 20:00'	System	18 Sep 2020 00:00:12

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:27:42', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c3c7b914-0884-448f-ba38-fc936a3c3b4b' User entered 'None (1)'	System	11 Sep 2020 14:28:09
	System	11 Sep 2020 14:28:09

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:27:46', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c3c7b914-0884-448f-ba38-fc936a3c3b4b' User entered 'No (N)'	System	11 Sep 2020 14:28:09
	System	11 Sep 2020 14:28:09

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:27:49', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c3c7b914-0884-448f-ba38-fc936a3c3b4b' User entered 'No (N)'	System	11 Sep 2020 14:28:09
	System	11 Sep 2020 14:28:09

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c3c7b914-0884-448f-ba38-fc936a3c3b4b' User entered 'None (1)'	System	11 Sep 2020 14:28:09
	System	11 Sep 2020 14:28:09

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:06', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c3c7b914-0884-448f-ba38-fc936a3c3b4b' User entered '11 Sep 2020 10:28'	System	11 Sep 2020 14:28:09
	System	11 Sep 2020 14:28:09

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 10:10'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 12:40'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:24', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c7db14f1-e72b-4be3-9ae2-7970cfcea3fc' User entered 'None (1)'	System	12 Sep 2020 00:11:58
	System	12 Sep 2020 00:11:58

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:28', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c7db14f1-e72b-4be3-9ae2-7970cfcea3fc' User entered 'No (N)'	System	12 Sep 2020 00:11:58
	System	12 Sep 2020 00:11:58

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:38', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c7db14f1-e72b-4be3-9ae2-7970cfcea3fc' User entered 'No (N)'	System	12 Sep 2020 00:11:58
	System	12 Sep 2020 00:11:58

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:43', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c7db14f1-e72b-4be3-9ae2-7970cfcea3fc' User entered 'None (1)'	System	12 Sep 2020 00:11:58
	System	12 Sep 2020 00:11:58

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:11:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c7db14f1-e72b-4be3-9ae2-7970cfcea3fc' User entered '11 Sep 2020 20:11'	System	12 Sep 2020 00:11:58
	System	12 Sep 2020 00:11:58

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 13:35'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 2'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:04:42', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b8b285a2-b1a3-433f-98b5-b51c0e9e1964' User entered 'None (1)'	System	13 Sep 2020 00:07:53
	System	13 Sep 2020 00:07:53

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:04:46', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b8b285a2-b1a3-433f-98b5-b51c0e9e1964' User entered 'No (N)'	System	13 Sep 2020 00:07:53
	System	13 Sep 2020 00:07:53

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:04:59', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b8b285a2-b1a3-433f-98b5-b51c0e9e1964' User entered 'No (N)'	System	13 Sep 2020 00:07:53
	System	13 Sep 2020 00:07:53

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:28', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b8b285a2-b1a3-433f-98b5-b51c0e9e1964' User entered 'None (1)'	System	13 Sep 2020 00:07:53
	System	13 Sep 2020 00:07:53

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b8b285a2-b1a3-433f-98b5-b51c0e9e1964'	System	13 Sep 2020 00:07:53
User entered '12 Sep 2020 20:05'	System	13 Sep 2020 00:07:53

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 3'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:06:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '375e6ad2-f8b8-4131-9066-aab9b1a45d46' User entered 'None (1)'	System	14 Sep 2020 00:08:13
	System	14 Sep 2020 00:08:13

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:06:03', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '375e6ad2-f8b8-4131-9066-aab9b1a45d46' User entered 'No (N)'	System	14 Sep 2020 00:08:13
	System	14 Sep 2020 00:08:13

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:06:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '375e6ad2-f8b8-4131-9066-aab9b1a45d46' User entered 'No (N)'	System	14 Sep 2020 00:08:13
	System	14 Sep 2020 00:08:13

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '375e6ad2-f8b8-4131-9066-aab9b1a45d46' User entered 'None (1)'	System	14 Sep 2020 00:08:13
	System	14 Sep 2020 00:08:13

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:28', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '375e6ad2-f8b8-4131-9066-aab9b1a45d46' User entered '13 Sep 2020 20:07'	System	14 Sep 2020 00:08:13
	System	14 Sep 2020 00:08:13

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 4'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:36:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '67f83b70-83cc-4f32-8e74-3173c20780ac' User entered 'None (1)'	System	15 Sep 2020 10:37:10
	System	15 Sep 2020 10:37:10

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:36:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '67f83b70-83cc-4f32-8e74-3173c20780ac'	System	15 Sep 2020 10:37:10
User entered 'No (N)'	System	15 Sep 2020 10:37:10

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:36:46', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '67f83b70-83cc-4f32-8e74-3173c20780ac' User entered 'No (N)'	System	15 Sep 2020 10:37:10
	System	15 Sep 2020 10:37:10

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:04', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '67f83b70-83cc-4f32-8e74-3173c20780ac' User entered 'None (1)'	System	15 Sep 2020 10:37:10
	System	15 Sep 2020 10:37:10

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:08', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '67f83b70-83cc-4f32-8e74-3173c20780ac' User entered '15 Sep 2020 06:37'	System	15 Sep 2020 10:37:10
	System	15 Sep 2020 10:37:10

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 5'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:54:45', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'bd6aa93d-d3c6-4ea2-9af6-86b38ab7f68a' User entered 'None (1)'	System	15 Sep 2020 23:56:20
	System	15 Sep 2020 23:56:20

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:54:51', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'bd6aa93d-d3c6-4ea2-9af6-86b38ab7f68a' User entered 'No (N)'	System	15 Sep 2020 23:56:20
	System	15 Sep 2020 23:56:20

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:54:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'bd6aa93d-d3c6-4ea2-9af6-86b38ab7f68a' User entered 'No (N)'	System	15 Sep 2020 23:56:20
	System	15 Sep 2020 23:56:20

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:55:35', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'bd6aa93d-d3c6-4ea2-9af6-86b38ab7f68a' User entered 'None (1)'	System	15 Sep 2020 23:56:20
	System	15 Sep 2020 23:56:20

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:55:39', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'bd6aa93d-d3c6-4ea2-9af6-86b38ab7f68a' User entered '15 Sep 2020 19:55'	System	15 Sep 2020 23:56:20
	System	15 Sep 2020 23:56:20

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 6'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:06', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c24fdcea-ea92-40e3-95e3-0c9deb6114e9' User entered 'None (1)'	System	17 Sep 2020 00:21:37
	System	17 Sep 2020 00:21:37

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c24fdcea-ea92-40e3-95e3-0c9deb6114e9' User entered 'No (N)'	System	17 Sep 2020 00:21:37
	System	17 Sep 2020 00:21:37

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c24fdcea-ea92-40e3-95e3-0c9deb6114e9' User entered 'No (N)'	System	17 Sep 2020 00:21:37
	System	17 Sep 2020 00:21:37

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:23', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c24fdcea-ea92-40e3-95e3-0c9deb6114e9' User entered 'None (1)'	System	17 Sep 2020 00:21:37
	System	17 Sep 2020 00:21:37

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'c24fdcea-ea92-40e3-95e3-0c9deb6114e9' User entered '16 Sep 2020 20:21'	System	17 Sep 2020 00:21:37
	System	17 Sep 2020 00:21:37

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 7'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '231adacd-f555-4a38-bbdb-806895de8fa4' User entered 'None (1)'	System	18 Sep 2020 00:00:41
	System	18 Sep 2020 00:00:41

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '231adacd-f555-4a38-bbdb-806895de8fa4' User entered 'No (N)'	System	18 Sep 2020 00:00:41
	System	18 Sep 2020 00:00:41

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:24', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '231adacd-f555-4a38-bbdb-806895de8fa4' User entered 'No (N)'	System	18 Sep 2020 00:00:41
	System	18 Sep 2020 00:00:41

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '231adacd-f555-4a38-bbdb-806895de8fa4' User entered 'None (1)'	System	18 Sep 2020 00:00:41
	System	18 Sep 2020 00:00:41

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:36', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '231adacd-f555-4a38-bbdb-806895de8fa4'	System	18 Sep 2020 00:00:41
User entered '17 Sep 2020 20:00'	System	18 Sep 2020 00:00:41

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:11', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered 'None (0)'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered 'None (0)'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered 'None (0)'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered 'None (0)'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:37', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered 'None (0)'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:28:40', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered 'None (0)'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:29:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered 'No (N)'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T10:29:18', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '7e3b1c77-7aef-4076-ac4c-7e35f6639335'	System	11 Sep 2020 14:29:24
User entered '11 Sep 2020 10:29'	System	11 Sep 2020 14:29:24

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 10:10'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 12:40'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:12:06', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970' User entered 'None (0)'	System	12 Sep 2020 00:13:31
	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:12:14', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970' User entered 'None (0)'	System	12 Sep 2020 00:13:31
	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:12:21', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970' User entered 'None (0)'	System	12 Sep 2020 00:13:31
	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:12:29', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970' User entered 'None (0)'	System	12 Sep 2020 00:13:31
	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:12:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970' User entered 'None (0)'	System	12 Sep 2020 00:13:31
	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:12:36', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970' User entered 'None (0)'	System	12 Sep 2020 00:13:31
	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:13:05', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970' User entered 'No (N)'	System	12 Sep 2020 00:13:31
	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-11T20:13:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '4d4afa56-6a18-4518-ba86-3709dfc76970'	System	12 Sep 2020 00:13:31
User entered '11 Sep 2020 20:13'	System	12 Sep 2020 00:13:31

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '11 Sep 2020 13:35'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 2'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:40', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered 'None (0)'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:43', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered 'None (0)'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:47', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered 'None (0)'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:50', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered 'None (0)'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered 'None (0)'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:05:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered 'None (0)'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:06:03', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered 'No (N)'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-12T20:06:06', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f428a030-10d3-4219-b5c5-3ed433034c45' User entered '12 Sep 2020 20:06'	System	13 Sep 2020 00:07:58
	System	13 Sep 2020 00:07:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 3'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb' User entered 'None (0)'	System	14 Sep 2020 00:08:19
	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:36', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb' User entered 'None (0)'	System	14 Sep 2020 00:08:19
	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:40', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb' User entered 'None (0)'	System	14 Sep 2020 00:08:19
	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:44', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb' User entered 'None (0)'	System	14 Sep 2020 00:08:19
	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:46', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb' User entered 'None (0)'	System	14 Sep 2020 00:08:19
	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:49', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb' User entered 'None (0)'	System	14 Sep 2020 00:08:19
	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:07:56', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb' User entered 'No (N)'	System	14 Sep 2020 00:08:19
	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-13T20:08:02', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '71c7d44a-d87c-49ea-a34b-b8e15c336ffb'	System	14 Sep 2020 00:08:19
User entered '13 Sep 2020 20:08'	System	14 Sep 2020 00:08:19

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 4'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered 'None (0)'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:20', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered 'None (0)'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:23', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered 'None (0)'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered 'None (0)'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:28', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered 'None (0)'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:31', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered 'None (0)'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:36', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered 'No (N)'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T06:37:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f48ce645-9852-48cb-ada1-692bdb9a81a4' User entered '15 Sep 2020 06:37'	System	15 Sep 2020 10:37:49
	System	15 Sep 2020 10:37:49

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 5'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:09', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered 'None (0)'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered 'None (0)'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:16', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered 'None (0)'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:19', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered 'None (0)'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:26', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered 'None (0)'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:29', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered 'None (0)'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered 'No (N)'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-15T19:56:37', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '848b75b7-b064-447b-8710-b6463669a03f' User entered '15 Sep 2020 19:56'	System	15 Sep 2020 23:56:48
	System	15 Sep 2020 23:56:48

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 6'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:38', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered 'None (0)'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:40', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered 'None (0)'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:43', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered 'None (0)'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:45', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered 'None (0)'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered 'None (0)'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:50', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered 'None (0)'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:53', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered 'No (N)'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-16T20:21:55', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51592767-fff3-4fb5-91af-e61de3c081cb' User entered '16 Sep 2020 20:21'	System	17 Sep 2020 00:21:58
	System	17 Sep 2020 00:21:58

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	11 Sep 2020 13:52:30
User entered 'Day 7'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:44', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d'	System	18 Sep 2020 00:01:18
User entered 'No interference with activity (1)'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:47', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d' User entered 'None (0)'	System	18 Sep 2020 00:01:18
	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:49', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d' User entered 'None (0)'	System	18 Sep 2020 00:01:18
	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d' User entered 'None (0)'	System	18 Sep 2020 00:01:18
	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:54', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d' User entered 'None (0)'	System	18 Sep 2020 00:01:18
	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:00:57', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d' User entered 'None (0)'	System	18 Sep 2020 00:01:18
	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:01:10', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d' User entered 'No (N)'	System	18 Sep 2020 00:01:18
	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-09-17T20:01:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07636765-4b53-4ecd-a44c-6c76917beb0d' User entered '17 Sep 2020 20:01'	System	18 Sep 2020 00:01:18
	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 13:52:30

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	18 Sep 2020 00:01:18
User entered 'Day 8'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	18 Sep 2020 00:01:18
User entered 'Day 9'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	18 Sep 2020 00:01:18
User entered 'Day 8'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '18 Sep 2020 12:00'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	18 Sep 2020 00:01:18
User entered 'Day 9'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:01:18

US3412224

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:33:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:01:18

US3412224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:55:56

US3412224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:58
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 16:55:56

US3412224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Sep 2020 16:55:56

US3412224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:06:58
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:55:56

US3412224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:59:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:56:02

US3412224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	18 Sep 2020 16:56:02

US3412224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:07:25
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 13:37:48

US3412224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:07:25
User entered '25 Sep 2020'	Mason Urban (b) (4)	25 Sep 2020 13:37:48

US3412224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:25
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	25 Sep 2020 13:37:48

US3412224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:07:25
User entered empty.	Mason Urban (b) (4) (b) (4)	25 Sep 2020 13:37:48

US3412224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:07:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 13:37:54

US3412224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	25 Sep 2020 13:37:54

US3412224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:22
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	02 Oct 2020 16:20:03

US3412224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:08:22
User entered '2 Oct 2020'	Mason Urban (b) (4)	02 Oct 2020 16:20:03

US3412224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:22
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	02 Oct 2020 16:20:03

US3412224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:22
User entered empty.	Mason Urban (b) (4) (b) (4)	02 Oct 2020 16:20:03

US3412224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:08:25
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	02 Oct 2020 16:20:08

US3412224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	02 Oct 2020 16:20:08

US3412224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:49
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:05

US3412224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:49
User entered '07 Oct 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:05

US3412224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:49
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:05

US3412224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered 'VISIT3'	System	08 Oct 2020 17:09:05

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered empty.	System	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered empty.	System	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered empty.	System	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered empty.	System	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:09:55
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered empty.	System	08 Oct 2020 17:09:12

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55

US3412224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55

US3412224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:06:39
User closed query 'Per discussion please update to no to match source. Thank you. ' (Site from CRA).	(b) (4)	23 Oct 2020 16:06:36
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	19 Oct 2020 20:26:34
Query 'Per discussion please update to no to match source. Thank you. ' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	19 Oct 2020 20:25:11
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	19 Oct 2020 20:25:01
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	19 Oct 2020 20:25:01
User opened query 'Per discussion please update to no to match source. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 16:11:22
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:22

US3412224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:06:39
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4) (b) (4)	19 Oct 2020 20:26:34
User entered '07 Oct 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:22

US3412224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:12
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:37

US3412224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
User closed query 'Per GCL Lab Reconciliation: The Visit 3 Day 57 Immunogenicity Assessment Collection date is recorded as 07OCT2020, however, per GCL, the Collection date is recorded as 06OCT2020. Please clarify the correct Collection date and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 11:18:53
Query 'Per GCL Lab Reconciliation: The Visit 3 Day 57 Immunogenicity Assessment Collection date is recorded as 07OCT2020, however, per GCL, the Collection date is recorded as 06OCT2020. Please clarify the correct Collection date and update as appropriate.' answered with 'confirming the correct date is 07oct2020' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	27 Oct 2020 13:08:07
User opened query 'Per GCL Lab Reconciliation: The Visit 3 Day 57 Immunogenicity Assessment Collection date is recorded as 07OCT2020, however, per GCL, the Collection date is recorded as 06OCT2020. Please clarify the correct Collection date and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:14:33
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:10:12
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Oct 2020 17:09:50
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		08 Oct 2020 17:09:50
User entered '07 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:50
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	08 Oct 2020 17:09:37
User entered '07 Sep 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:37

US3412224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:10:12
User entered '09:15'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:37

US3412224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '07 Oct 2020 09:15'	System	08 Oct 2020 17:09:50
User entered '07 Sep 2020 09:15'	System	08 Oct 2020 17:09:37

US3412224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:12:13
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:09:55

US3412224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:55
User entered '1'	System	08 Oct 2020 17:09:55

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 64'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).		09 Nov 2020 13:59:19
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'PER PATIENT REPORTED CHANGES IN HEALTH DURING E-DIARY ENTRY. CALLED TO CLARIFY AND PATIENT HAD A MIGRANE. THIS IS PROVIDED ON MEDICAL HISTORY' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	06 Nov 2020 16:21:00
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:20:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-16T12:50:11', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d7d119f-019c-4a23-bd98-28f7385d6efe'	System	16 Oct 2020 16:51:16
User entered 'Yes (Y)'	System	16 Oct 2020 16:51:16

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-16T12:50:21', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d7d119f-019c-4a23-bd98-28f7385d6efe' User entered 'No (N)'	System	16 Oct 2020 16:51:16
	System	16 Oct 2020 16:51:16

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-16T12:50:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d7d119f-019c-4a23-bd98-28f7385d6efe' User entered 'No (N)'	System	16 Oct 2020 16:51:16
	System	16 Oct 2020 16:51:16

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-16T12:50:39', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d7d119f-019c-4a23-bd98-28f7385d6efe' User entered 'Yes (Y)'	System	16 Oct 2020 16:51:16
	System	16 Oct 2020 16:51:16

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Please 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)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-16T12:50:51', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d7d119f-019c-4a23-bd98-28f7385d6efe'	System	16 Oct 2020 16:51:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Oct 2020 16:51:16

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-16T12:51:03', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d7d119f-019c-4a23-bd98-28f7385d6efe' User entered '16 Oct 2020 12:51:03'	System	16 Oct 2020 16:51:16
	System	16 Oct 2020 16:51:16

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 71'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-22T07:04:13', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '55086788-6a03-4ef3-b00c-01ef8962858e' User entered 'No (N)'	System	22 Oct 2020 11:04:24
	System	22 Oct 2020 11:04:24

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-22T07:04:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '55086788-6a03-4ef3-b00c-01ef8962858e' User entered 'No (N)'	System	22 Oct 2020 11:04:24
	System	22 Oct 2020 11:04:24

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-22T07:04:22', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '55086788-6a03-4ef3-b00c-01ef8962858e' User entered '22 Oct 2020 07:04:22'	System	22 Oct 2020 11:04:24
	System	22 Oct 2020 11:04:24

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 78'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-28T20:04:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '66170965-9a4b-4dd3-b985-a4a030d50ee1' User entered 'No (N)'	System	29 Oct 2020 00:04:14
	System	29 Oct 2020 00:04:14

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-28T20:04:07', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '66170965-9a4b-4dd3-b985-a4a030d50ee1' User entered 'No (N)'	System	29 Oct 2020 00:04:14
	System	29 Oct 2020 00:04:14

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-10-28T20:04:12', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '66170965-9a4b-4dd3-b985-a4a030d50ee1' User entered '28 Oct 2020 20:04:12'	System	29 Oct 2020 00:04:14
	System	29 Oct 2020 00:04:14

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 92'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-11T06:24:09', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0a5130fb-9438-4866-a6e7-ea4973952f08' User entered 'No (N)'	System	11 Nov 2020 11:24:44
	System	11 Nov 2020 11:24:44

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-11T06:24:24', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0a5130fb-9438-4866-a6e7-ea4973952f08'	System	11 Nov 2020 11:24:44
User entered 'No (N)'	System	11 Nov 2020 11:24:44

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-11T06:24:40', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0a5130fb-9438-4866-a6e7-ea4973952f08' User entered '11 Nov 2020 06:24:40'	System	11 Nov 2020 11:24:44
	System	11 Nov 2020 11:24:44

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered 'Day 99'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-18T06:31:18', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f1479c37-2d2f-4cf2-9e3a-78b395c8dca3'	System	18 Nov 2020 11:31:43
User entered 'No (N)'	System	18 Nov 2020 11:31:43

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-18T06:31:25', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f1479c37-2d2f-4cf2-9e3a-78b395c8dca3'	System	18 Nov 2020 11:31:43
User entered 'No (N)'	System	18 Nov 2020 11:31:43

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-18T06:31:42', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f1479c37-2d2f-4cf2-9e3a-78b395c8dca3' User entered '18 Nov 2020 06:31:42'	System	18 Nov 2020 11:31:43
	System	18 Nov 2020 11:31:43

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 17:02:09

US3412224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:50:20
Data entry locked.	System	14 Aug 2020 17:02:09
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 17:02:09

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:20:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b'	System	25 Nov 2020 13:23:40
User entered 'Yes (Y)'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:20:42', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b'	System	25 Nov 2020 13:23:40
User entered 'No (N)'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:02', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered 'Yes (Y)'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b'	System	25 Nov 2020 13:23:40
User entered '1'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '1'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b'	System	25 Nov 2020 13:23:40
User entered '1'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:22:52', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '0'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Please 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:23:04', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b'	System	25 Nov 2020 13:23:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:23:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b'	System	25 Nov 2020 13:23:40
User entered 'No (N)'	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-11-25T08:23:32', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '88ab9589-d1f5-483a-a7ea-818f7d0e992b' User entered '25 Nov 2020 08:23:32'	System	25 Nov 2020 13:23:40
	System	25 Nov 2020 13:23:40

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-01T16:46:08', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'ddd99b64-539d-429d-a709-e373b73ae26e' User entered 'No (N)'	System	01 Dec 2020 21:46:23
	System	01 Dec 2020 21:46:23

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-01T16:46:15', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'ddd99b64-539d-429d-a709-e373b73ae26e'	System	01 Dec 2020 21:46:23
User entered 'No (N)'	System	01 Dec 2020 21:46:23

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-01T16:46:20', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'ddd99b64-539d-429d-a709-e373b73ae26e' User entered '01 Dec 2020 16:46:20'	System	01 Dec 2020 21:46:23
	System	01 Dec 2020 21:46:23

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-09T09:42:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3797f869-95fe-40d6-89a7-5e93c4c7b13e' User entered 'No (N)'	System	09 Dec 2020 14:43:05
	System	09 Dec 2020 14:43:05

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-09T09:42:57', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3797f869-95fe-40d6-89a7-5e93c4c7b13e' User entered 'No (N)'	System	09 Dec 2020 14:43:05
	System	09 Dec 2020 14:43:05

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-09T09:43:01', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '3797f869-95fe-40d6-89a7-5e93c4c7b13e' User entered '09 Dec 2020 09:43:01'	System	09 Dec 2020 14:43:05
	System	09 Dec 2020 14:43:05

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-13T19:09:22', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a7f12373-13ca-4fbd-adf7-4f7240ef2134' User entered 'No (N)'	System	14 Dec 2020 00:09:37
	System	14 Dec 2020 00:09:37

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-13T19:09:29', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a7f12373-13ca-4fbd-adf7-4f7240ef2134' User entered 'No (N)'	System	14 Dec 2020 00:09:37

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-13T19:09:34', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'a7f12373-13ca-4fbd-adf7-4f7240ef2134' User entered '13 Dec 2020 19:09:34'	System	14 Dec 2020 00:09:37
	System	14 Dec 2020 00:09:37

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-22T18:03:51', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '419e023b-50fc-4187-abe5-5c60f6861eae' User entered 'No (N)'	System	22 Dec 2020 23:04:01
	System	22 Dec 2020 23:04:01

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-22T18:03:54', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '419e023b-50fc-4187-abe5-5c60f6861eae' User entered 'No (N)'	System	22 Dec 2020 23:04:01
	System	22 Dec 2020 23:04:01

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-22T18:03:58', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '419e023b-50fc-4187-abe5-5c60f6861eae' User entered '22 Dec 2020 18:03:58'	System	22 Dec 2020 23:04:01
	System	22 Dec 2020 23:04:01

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-27T07:19:06', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51bb0401-72f7-4a3f-9056-96612361468f' User entered 'No (N)'	System	27 Dec 2020 12:19:35
	System	27 Dec 2020 12:19:35

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-27T07:19:22', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51bb0401-72f7-4a3f-9056-96612361468f' User entered 'No (N)'	System	27 Dec 2020 12:19:35
	System	27 Dec 2020 12:19:35

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2020-12-27T07:19:30', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '51bb0401-72f7-4a3f-9056-96612361468f' User entered '27 Dec 2020 07:19:30'	System	27 Dec 2020 12:19:35
	System	27 Dec 2020 12:19:35

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-03T00:35:24', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0c3badd-448a-4481-8274-b26729531bf8'	System	03 Jan 2021 05:35:36
User entered 'No (N)'	System	03 Jan 2021 05:35:36

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-03T00:35:28', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0c3badd-448a-4481-8274-b26729531bf8' User entered 'No (N)'	System	03 Jan 2021 05:35:36
	System	03 Jan 2021 05:35:36

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-03T00:35:33', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0c3badd-448a-4481-8274-b26729531bf8' User entered '03 Jan 2021 00:35:33'	System	03 Jan 2021 05:35:36
	System	03 Jan 2021 05:35:36

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-10T08:05:18', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0e730f56-762b-41a2-9bec-401a0fb39f2c' User entered 'No (N)'	System	10 Jan 2021 13:05:30
	System	10 Jan 2021 13:05:30

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-10T08:05:21', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0e730f56-762b-41a2-9bec-401a0fb39f2c'	System	10 Jan 2021 13:05:30
User entered 'No (N)'	System	10 Jan 2021 13:05:30

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-10T08:05:25', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '0e730f56-762b-41a2-9bec-401a0fb39f2c' User entered '10 Jan 2021 08:05:25'	System	10 Jan 2021 13:05:30
	System	10 Jan 2021 13:05:30

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-17T17:55:17', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'be69609f-d47e-4ad3-b8ab-aeab9018c39e'	System	24 Jan 2021 05:05:44
User entered 'No (N)'	System	24 Jan 2021 05:05:44

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-17T17:55:32', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'be69609f-d47e-4ad3-b8ab-aeab9018c39e'	System	24 Jan 2021 05:05:44
User entered 'No (N)'	System	24 Jan 2021 05:05:44

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-17T17:55:37', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'be69609f-d47e-4ad3-b8ab-aeab9018c39e' User entered '17 Jan 2021 17:55:37'	System	24 Jan 2021 05:05:44

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-24T00:05:49', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30d1442c-d7cb-41e1-9e47-68b9dabed8d2'	System	24 Jan 2021 05:06:01
User entered 'No (N)'	System	24 Jan 2021 05:06:01

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-24T00:05:53', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30d1442c-d7cb-41e1-9e47-68b9dabed8d2'	System	24 Jan 2021 05:06:01
User entered 'No (N)'	System	24 Jan 2021 05:06:01

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-24T00:05:57', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '30d1442c-d7cb-41e1-9e47-68b9dabed8d2' User entered '24 Jan 2021 00:05:57'	System	24 Jan 2021 05:06:01
	System	24 Jan 2021 05:06:01

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-31T00:03:05', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'd0e2182c-e454-4d8f-9b3c-aa50a9a49850' User entered 'No (N)'	System	01 Feb 2021 01:06:32
	System	01 Feb 2021 01:06:32

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-31T00:03:09', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'd0e2182c-e454-4d8f-9b3c-aa50a9a49850'	System	01 Feb 2021 01:06:32
User entered 'No (N)'	System	01 Feb 2021 01:06:32

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-01-31T00:03:14', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'd0e2182c-e454-4d8f-9b3c-aa50a9a49850' User entered '31 Jan 2021 00:03:14'	System	01 Feb 2021 01:06:32
	System	01 Feb 2021 01:06:32

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-07T02:31:44', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8a6422ae-fed0-4ca1-8f9b-b0dc332e7d27'	System	07 Feb 2021 07:31:52
User entered 'No (N)'	System	07 Feb 2021 07:31:52

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-07T02:31:46', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8a6422ae-fed0-4ca1-8f9b-b0dc332e7d27'	System	07 Feb 2021 07:31:52
User entered 'No (N)'	System	07 Feb 2021 07:31:52

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-07T02:31:50', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8a6422ae-fed0-4ca1-8f9b-b0dc332e7d27'	System	07 Feb 2021 07:31:52
User entered '07 Feb 2021 02:31:50'	System	07 Feb 2021 07:31:52

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-15T21:58:20', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b72b805b-db13-478b-9125-886b7fd0b1aa'	System	16 Feb 2021 02:58:31
User entered 'No (N)'	System	16 Feb 2021 02:58:31

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-15T21:58:22', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b72b805b-db13-478b-9125-886b7fd0b1aa'	System	16 Feb 2021 02:58:31
User entered 'No (N)'	System	16 Feb 2021 02:58:31

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-15T21:58:27', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b72b805b-db13-478b-9125-886b7fd0b1aa'	System	16 Feb 2021 02:58:31
User entered '15 Feb 2021 21:58:27'	System	16 Feb 2021 02:58:31

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-21T01:54:41', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e202591f-de19-4454-bc1c-4c6d7b583973' User entered 'No (N)'	System	21 Feb 2021 06:54:51
	System	21 Feb 2021 06:54:51

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-21T01:54:43', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e202591f-de19-4454-bc1c-4c6d7b583973' User entered 'No (N)'	System	21 Feb 2021 06:54:51
	System	21 Feb 2021 06:54:51

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-21T01:54:48', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'e202591f-de19-4454-bc1c-4c6d7b583973' User entered '21 Feb 2021 01:54:48'	System	21 Feb 2021 06:54:51
	System	21 Feb 2021 06:54:51

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-28T10:16:21-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b1173640-9443-47cd-a532-49314032d6c9'	System	28 Feb 2021 15:16:35
User entered 'No (N)'	System	28 Feb 2021 15:16:35

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-28T10:16:26-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b1173640-9443-47cd-a532-49314032d6c9'	System	28 Feb 2021 15:16:35
User entered 'No (N)'	System	28 Feb 2021 15:16:35

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-02-28T10:16:29-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'b1173640-9443-47cd-a532-49314032d6c9'	System	28 Feb 2021 15:16:35
User entered '28 Feb 2021 15:16:29'	System	28 Feb 2021 15:16:35

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-07T00:02:43-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '803c45ba-8e6e-42c4-9966-58b07c5eb34a'	System	07 Mar 2021 05:04:47
User entered 'No (N)'	System	07 Mar 2021 05:04:47

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-07T00:02:45-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '803c45ba-8e6e-42c4-9966-58b07c5eb34a'	System	07 Mar 2021 05:04:47
User entered 'No (N)'	System	07 Mar 2021 05:04:47

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-07T00:02:49-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '803c45ba-8e6e-42c4-9966-58b07c5eb34a' User entered '07 Mar 2021 00:02:49'	System	07 Mar 2021 05:04:47
	System	07 Mar 2021 05:04:47

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-14T21:28:00-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07b8cbbe-4b3c-4eec-a038-9207d3df22f7'	System	15 Mar 2021 01:28:29
User entered 'No (N)'	System	15 Mar 2021 01:28:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-14T21:28:05-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07b8cbbe-4b3c-4eec-a038-9207d3df22f7'	System	15 Mar 2021 01:28:29
User entered 'No (N)'	System	15 Mar 2021 01:28:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-14T21:28:26-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '07b8cbbe-4b3c-4eec-a038-9207d3df22f7'	System	15 Mar 2021 01:28:29
User entered '14 Mar 2021 21:28:26'	System	15 Mar 2021 01:28:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-22T20:00:16-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cb13b263-6a15-461a-ba06-ebfafa62a02b'	System	23 Mar 2021 00:01:29
User entered 'Yes (Y)'	System	23 Mar 2021 00:01:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-22T20:00:08-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cb13b263-6a15-461a-ba06-ebfafa62a02b'	System	23 Mar 2021 00:01:29
User entered 'No (N)'	System	23 Mar 2021 00:01:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-22T20:00:07-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cb13b263-6a15-461a-ba06-ebfafa62a02b'	System	23 Mar 2021 00:01:29
User entered 'No (N)'	System	23 Mar 2021 00:01:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-22T20:00:06-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cb13b263-6a15-461a-ba06-ebfafa62a02b'	System	23 Mar 2021 00:01:29
User entered 'Yes (Y)'	System	23 Mar 2021 00:01:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Please 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-22T20:00:06-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cb13b263-6a15-461a-ba06-ebfafa62a02b'	System	23 Mar 2021 00:01:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Mar 2021 00:01:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-22T20:00:54-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'cb13b263-6a15-461a-ba06-ebfafa62a02b'	System	23 Mar 2021 00:01:29
User entered '22 Mar 2021 20:00:54'	System	23 Mar 2021 00:01:29

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-28T09:22:24-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '919d7326-ec3a-4d80-87f8-c14dcff55ddb'	System	28 Mar 2021 13:22:36
User entered 'No (N)'	System	28 Mar 2021 13:22:36

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-28T09:22:28-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '919d7326-ec3a-4d80-87f8-c14dcff55ddb'	System	28 Mar 2021 13:22:36
User entered 'No (N)'	System	28 Mar 2021 13:22:36

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-28T09:22:32-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '919d7326-ec3a-4d80-87f8-c14dcff55ddb' User entered '28 Mar 2021 09:22:32'	System	28 Mar 2021 13:22:36
	System	28 Mar 2021 13:22:36

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-04T21:36:06-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d687da1-3b80-4da8-85b0-0aa472f37d59'	System	05 Apr 2021 01:36:18
User entered 'No (N)'	System	05 Apr 2021 01:36:18

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-04T21:36:10-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d687da1-3b80-4da8-85b0-0aa472f37d59'	System	05 Apr 2021 01:36:18
User entered 'No (N)'	System	05 Apr 2021 01:36:18

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-04T21:36:14-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '8d687da1-3b80-4da8-85b0-0aa472f37d59'	System	05 Apr 2021 01:36:18
User entered '04 Apr 2021 21:36:14'	System	05 Apr 2021 01:36:18

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-11T18:48:22-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '72cbb2f3-a3ae-4069-9a37-1688a59779a1' User entered 'No (N)'	System	11 Apr 2021 22:48:42
	System	11 Apr 2021 22:48:42

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-11T18:48:27-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '72cbb2f3-a3ae-4069-9a37-1688a59779a1'	System	11 Apr 2021 22:48:42
User entered 'No (N)'	System	11 Apr 2021 22:48:42

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-11T18:48:36-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '72cbb2f3-a3ae-4069-9a37-1688a59779a1'	System	11 Apr 2021 22:48:42
User entered '11 Apr 2021 18:48:36'	System	11 Apr 2021 22:48:42

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-18T00:02:34-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f30e9531-f3cd-4016-ba95-f707ea76814c'	System	18 Apr 2021 04:03:42
User entered 'No (N)'	System	18 Apr 2021 04:03:42

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-18T00:02:36-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f30e9531-f3cd-4016-ba95-f707ea76814c'	System	18 Apr 2021 04:03:42
User entered 'No (N)'	System	18 Apr 2021 04:03:42

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-18T00:02:40-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f30e9531-f3cd-4016-ba95-f707ea76814c'	System	18 Apr 2021 04:03:42
User entered '18 Apr 2021 00:02:40'	System	18 Apr 2021 04:03:42

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-25T10:27:42-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f1aa2c5c-4c54-45bd-99d1-39c35d73eeff' User entered 'No (N)'	System	25 Apr 2021 14:27:57
	System	25 Apr 2021 14:27:57

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-25T10:27:46-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f1aa2c5c-4c54-45bd-99d1-39c35d73eeff' User entered 'No (N)'	System	25 Apr 2021 14:27:57

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-04-25T10:27:54-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'f1aa2c5c-4c54-45bd-99d1-39c35d73eeff' User entered '25 Apr 2021 10:27:54'	System	25 Apr 2021 14:27:57
	System	25 Apr 2021 14:27:57

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-05-02T08:16:04-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'dea3e39d-3eee-4ba3-80dd-dfec542e0c2e'	System	02 May 2021 12:16:13
User entered 'No (N)'	System	02 May 2021 12:16:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Have you been exposed to someone with 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 (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-05-02T08:16:07-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'dea3e39d-3eee-4ba3-80dd-dfec542e0c2e'	System	02 May 2021 12:16:13
User entered 'No (N)'	System	02 May 2021 12:16:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-05-02T08:16:10-04:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: 'dea3e39d-3eee-4ba3-80dd-dfec542e0c2e'	System	02 May 2021 12:16:13
User entered '02 May 2021 08:16:10'	System	02 May 2021 12:16:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 05:46:13

US3412224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:33:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:46:13
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 05:46:13

US3412224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:33:31

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)	26 Apr 2021 00:35:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-04T14:06:39-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '73d3babe-e560-4a11-92eb-c4b4b7773e79'	System	04 Mar 2021 19:06:49
User entered 'No (N)'	System	04 Mar 2021 19:06:49

US3412224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:33:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:35:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E4F9A84B-003A-4F43-823E-16341141CF73)', Time: '2021-03-04T14:06:43-05:00', User OID: 'PatientReportedOutcome (US3412224)', ODM File OID: '73d3babe-e560-4a11-92eb-c4b4b7773e79' User entered '04 Mar 2021 14:06:43'	System	04 Mar 2021 19:06:49
	System	04 Mar 2021 19:06:49

US3412224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:36
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Nov 2020 17:31:54

US3412224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:36
User entered '4 Nov 2020'	Mason Urban (b) (4) (b) (4)	04 Nov 2020 17:31:54

US3412224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:36
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	04 Nov 2020 17:31:54

US3412224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:36
User entered empty.	Mason Urban (b) (4) (b) (4)	04 Nov 2020 17:31:54

US3412224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:18:42
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	04 Nov 2020 17:33:01

US3412224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:10:52
User entered 'I'	System	04 Nov 2020 17:33:01

US3412224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:38:34
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Feb 2021 15:02:05
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Dec 2020 15:50:56

US3412224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:38:34
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	10 Feb 2021 15:02:05
User entered '9 Dec 2020'	Mason Urban (b) (4)	09 Dec 2020 15:50:56

US3412224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:38:34
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	10 Feb 2021 15:02:05
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Dec 2020 15:50:56

US3412224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:38:34
User entered 'subject was in convalescent phase of the study and therefor no contact was attempted.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 15:02:05
User entered empty.	Mason Urban (b) (4) (b) (4)	09 Dec 2020 15:50:56

US3412224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:38:40
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	09 Dec 2020 15:51:01

US3412224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User entered 'I'	System	09 Dec 2020 15:51:01

US3412224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:36
User entered 'Yes (Y)'	Mason Urban (b) (4)	07 Jan 2021 20:10:46

US3412224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:36
User entered '7 Jan 2021'	Mason Urban (b) (4) (b) (4)	07 Jan 2021 20:10:46

US3412224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:36
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	07 Jan 2021 20:10:46

US3412224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:36
User entered empty.	Mason Urban (b) (4) (b) (4)	07 Jan 2021 20:10:46

US3412224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:59:40
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	07 Jan 2021 20:10:52

US3412224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User entered 'I'	System	07 Jan 2021 20:10:52

US3412224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:14
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Feb 2021 16:25:33

US3412224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:14
User entered '5 Feb 2021'	Mason Urban (b) (4) (b) (4)	05 Feb 2021 16:25:33

US3412224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:14
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	05 Feb 2021 16:25:33

US3412224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:14
User entered empty.	Mason Urban (b) (4) (b) (4)	05 Feb 2021 16:25:33

US3412224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:18
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	05 Feb 2021 16:25:40

US3412224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:39:40
User entered 'I'	System	05 Feb 2021 16:25:40

US3412224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:33
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:54:15

US3412224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:33
User entered '09 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:54:15

US3412224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[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 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:33
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:54:15

US3412224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered 'VISIT4'	System	12 Mar 2021 13:54:15

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered 'Yes (Y)'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered '09 Mar 2021'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered '15:20'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered '09 Mar 2021 15:20'	System	31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered '36.5' C		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered 'Oral (Oral)'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered empty.		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered '66'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered 'bpm'	System	31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered '16'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered 'breaths/min'	System	31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered '122'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered 'mmHg'	System	31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:33:28
User entered '90'		31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered 'mmHg'	System	31 Mar 2021 19:56:30

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32

US3412224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32

US3412224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:41
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:54:50

US3412224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:41
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:54:50

US3412224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:57
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:55:08

US3412224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:57
User entered '09 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:55:08

US3412224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:41:57
User entered '15:36'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:55:08

US3412224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered '09 Mar 2021 15:36'	System	12 Mar 2021 13:55:08

US3412224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:42:09
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 13:55:12

US3412224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:54:32
User entered 'I'	System	12 Mar 2021 13:55:12

US3412224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 18:21:05

US3412224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:58
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 18:21:05

US3412224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Apr 2021 18:21:05

US3412224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:38:58
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 18:21:05

US3412224

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:39:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 18:21:08

US3412224

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:21:08

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:02:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 25-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 25-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate.' (Site from DM).		14 Dec 2020 12:04:44
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 25-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 25-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate.' answered with 'Site is obtaining saliva samples from subject.' (Site from DM).	Steven Anderson (b) (4) (b) (4)	10 Dec 2020 19:34:08
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 25-NOV-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 25-NOV-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 07:08:21
User entered '25 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:47:02

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:25:58
User closed query 'Please confirm time of contact' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 13:25:55
Query 'Please confirm time of contact' answered with 'PER SOURCE TIME COLLECTED IS 09:54' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:21:18
DataPoint Un-verified.	(b) (4), (b) (6)	27 Jan 2021 21:02:33
DataPoint Verified.		27 Jan 2021 21:02:30
User opened query 'Please confirm time of contact' (Site from CRA).		27 Jan 2021 21:02:12
User entered '09:54'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:47:02

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:11
User entered '25 Nov 2020 09:54'	System	02 Dec 2020 16:47:02

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:02:30
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:47:02

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:33:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:02:30
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:47:02

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 1 (Day 1)'	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered '23 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User closed query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 and Day 2. Please reconcile and update accordingly ' (Site from DM).		18 Jan 2021 11:26:26
Query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 and Day 2. Please reconcile and update accordingly ' answered with 'UPDATED TO ND' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 14:45:24
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 14:45:08
User opened query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 and Day 2. Please reconcile and update accordingly ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 07:27:41
User entered '1'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 14:45:08
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	14 Jan 2021 14:45:08
User entered empty.	System	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 14:45:08
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:04:52
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:04:57
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:04:59
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:23
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:55:03
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:20

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 2 (Day 2)'	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered '24 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 14:45:44
User entered '1'	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 14:45:44
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	14 Jan 2021 14:45:44
User entered empty.	System	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 14:45:44
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:05:38
User entered 'None (None)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 16:57:10
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 16:49:34

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 3 (Day 3)'	Jacob sekinger (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered '25 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User closed query 'Per CDM: it appears that O2 Saturation was not collected for Day 3. (25 NOV 2020) If not collected please consider recording these as Not Done ' (Site from DM).		18 Jan 2021 11:26:42
Query 'Per CDM: it appears that O2 Saturation was not collected for Day 3. (25 NOV 2020) If not collected please consider recording these as Not Done ' answered with 'UPDATED TO NOT DONE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 14:46:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 14:46:14
User opened query 'Per CDM: it appears that O2 Saturation was not collected for Day 3. (25 NOV 2020) If not collected please consider recording these as Not Done ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 07:29:18
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	14 Jan 2021 14:46:14
User entered empty.	System	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered '36.8' C	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:07:33
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:07:42
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:08:07
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:07:28
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 16:53:29

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 8 (Day 8)'	Jacob sekinger (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered '30 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:28:31
User entered '93'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:28:30
User entered '99.8' F	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:28:37
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:28:42
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:28:50
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:28:56
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:28:59
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:00
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:14
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:29
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:29:16
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:00:45

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 9 (Day 9)'	Jacob sekinger (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered '1 Dec 2020'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:31:52
User entered '95'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	02 Dec 2020 17:08:18

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:31:54
User entered '98.8' F	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:31:59
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:02
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:07
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:09
User entered 'Moderate (Moderate)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:13
User entered 'Mild (Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:31
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:08:18

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 10 (Day 10)'	Melissa Fuson (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered '2 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered '0'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:54
User entered '95'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	02 Dec 2020 19:59:46

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:32:56
User entered '97.7' F	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:01
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:05
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:33:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 19:59:46

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 4 (Day 4)'	Melissa Fuson (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered '26 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered 'I'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered empty.	System	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:36:09
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:32:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 18:23:30
Signature has been broken.		20 Apr 2021 18:23:30
User entered 'Not Done (Not Done)' reason for change: Data Entry Error		20 Apr 2021 18:23:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:16:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:29:11

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 25 Nov 2020 symptom log on log line 8. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 19:04:09
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 25 Nov 2020 symptom log on log line 8. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'information has been updated' (Site from DM).		20 Apr 2021 18:24:23
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 25 Nov 2020 symptom log on log line 8. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).		20 Apr 2021 09:19:19
User signature succeeded.		16 Apr 2021 14:45:40
User entered 'Day 5 (Day 5)'	Richard Powell (b) (4) (b) (4) Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered '27 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:04
User entered '94'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:05
User entered '98.2' F	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:11
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:15
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:22
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:24
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:34:52
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 14:33:01
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	20 Apr 2021 17:43:59
DataPoint Un-verified.	Andrea Newlands (b) (4)	20 Apr 2021 17:43:37
Signature has been broken.	Andrea Newlands (b) (4)	20 Apr 2021 17:43:37
User entered 'None (None)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	20 Apr 2021 17:43:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:25:39
User entered empty.	Melissa Fuson (b) (4)	04 Dec 2020 14:32:13

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 6 (Day 6)'	Melissa Fuson (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered '28 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:05
User entered '96'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:07
User entered '98.9' F	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:12
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:16
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:22
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:24
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:32
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:30
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:26:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:39:40

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 7 (Day 7)'	(b) (4) Melissa Fuson (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered '29 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:05
User entered '95'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:07
User entered '98.7' F	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:11
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:16
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:23
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:27:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:44:05

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 11 (Day 11)' reason for change:	(b) (4)	
Data Entry Error	Melissa Fuson (b) (4)	04 Dec 2020 14:49:08
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	04 Dec 2020 14:48:51
	(b) (4)	

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:05
User entered '98'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:04
User entered '97.7' F	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:09
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:15
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:20
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:48:51

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 12 (Day 12)'	(b) (4) Melissa Fuson (b) (4)	10 Dec 2020 14:07:36

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered '4 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered '0'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:51
User entered '97'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:53
User entered '97.7' F	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:34:57
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:02
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:07
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:09
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:07:36

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 13 (Day 13)'	Melissa Fuson (b) (4)	10 Dec 2020 14:10:19

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered '5 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered '0'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:51
User entered '98'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:52
User entered '96.8' F	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:35:58
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:03
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:13
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:10:19

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 14 (Day 14)'	Melissa Fuson (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered '6 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered '0'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:44
User entered '98'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:46
User entered '95.9' F	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Form: Symptom Log (14)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:36:52
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Form: Symptom Log (14)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

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[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User closed query 'None per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:23
DataPoint Verified.		28 Jan 2021 20:42:21
Query 'None per source. Please confirm and update as appropriate' answered with 'UPDATED TO NONE PER SOURCE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:12:40
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:12:19
User opened query 'None per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:37:14
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (14)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Form: Symptom Log (14)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:37:47
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Folder: Covid-19 Assessment 25 Nov 2020

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User closed query 'Please complete' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 20:42:26
Query 'Please complete' answered with 'UPDATED TO NONE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:17:25
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:12:19
User opened query 'Please complete' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:37:58
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User closed query 'Please complete' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 20:42:28
Query 'Please complete' answered with 'UPDATED TO NONE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:17:31
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:12:19
User opened query 'Please complete' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:38:09
DataPoint Un-verified.		27 Jan 2021 21:38:04
DataPoint Verified.		27 Jan 2021 21:38:00
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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Form: Symptom Log (14)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User closed query 'Please complete' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 20:42:33
Query 'Please complete' answered with 'UPDATED TO NONE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:17:40
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:12:19
User opened query 'Please complete' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:38:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:42:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:13:57

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 15 (Day 15)'	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User closed query 'Please complete severity for each symptom on this page' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 20:43:38
Query 'Please complete severity for each symptom on this page' answered with 'UPDATED ALL SEVERITY FOR EACH SYMPTOM' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:18:55
User opened query 'Please complete severity for each symptom on this page' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:39:58
User entered '7 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:18:24

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Form: Symptom Log (15)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered '0'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:39:04
User entered '97' reason for change: Data Entry Error	Melissa Fuson (b) (4)	10 Dec 2020 14:18:43
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	10 Dec 2020 14:18:43
User entered empty.	System	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:39:06
User entered '97.5' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	10 Dec 2020 14:18:43
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Form: Symptom Log (15)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:39:16
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

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[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

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[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Form: Symptom Log (15)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User closed query 'Mild congestion per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:43:45
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:43:42
Query 'Mild congestion per source. Please confirm and update as appropriate' answered with 'UPDATED TO MILD' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:15:36
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:14:33
User opened query 'Mild congestion per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:39:33
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:18:24

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User closed query 'No runny nose per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:43:49
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 20:43:47
Query 'No runny nose per source. Please confirm and update as appropriate' answered with 'UPDATED TO NONE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:15:43
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 20:14:33
User opened query 'No runny nose per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:39:45
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:18:24

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

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Form: Symptom Log (15)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:44:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 20:14:33
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 14:18:24

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
User entered 'Day 16 (Day 16)'	Melissa Fuson (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered '8 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered '0'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:36
User entered '98'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User entered '%'	System	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:37
User entered '97.0' F	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:33:31

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 14:20:21

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[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 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[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 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		11 Dec 2020 10:55:06
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'this was entered in adverse events' (Site from System).	Steven Anderson (b) (4)	10 Dec 2020 19:34:27
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 13:57:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 13:57:23
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	10 Dec 2020 13:57:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	10 Dec 2020 13:57:23
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 13:56:37
User entered empty.	Melissa Fuson (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[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 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:40:59
User entered empty.	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:56:37

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:33:31

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:35
User entered 'I'	System	10 Dec 2020 13:57:23

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered 'No (N)'	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered empty.	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered empty.	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered empty.	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered 'No (N)'	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered empty.	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered empty.	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered empty.	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered 'Yes (Y)'	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

US3412224

Folder: Covid-19 Assessment 25 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:33:31

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered '30 Nov 2020'	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

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Folder: Covid-19 Assessment 25 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
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[Oxygen Saturation](#)

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User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
User entered '93'	Steven Anderson (b) (4)	10 Dec 2020 19:31:22

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
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[PaO2](#)

Audit	User	Time (GMT)
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User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
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Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:21
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[High-Flow Oxygen?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
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[Mechanical Ventilation?](#)

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User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
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[ECMO?](#)

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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[Evidence of Shock Requires
Vasopressors](#)

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[Acute Renal Dysfunction?](#)

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[Hepatic Dysfunction?](#)

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[Neurologic Dysfunction?](#)

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[Clinical Evidence](#)

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[Radiographical Evidence](#)

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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Folder: Covid-19 Assessment 25 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:33:31

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:07:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:25
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 14:49:37

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:33:31

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-9 = 10DEC2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF.Thanks ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 04:51:26
Query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-9 = 10DEC2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF.Thanks ' answered with 'edc is correct, will update with ppd ' (Site from DM).	Andrea Newlands (b) (4)	24 Mar 2021 13:23:32
User opened query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-9 = 10DEC2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF.Thanks ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 09:33:54
User accepted default value 'Day 3 (Day 3)'	Melissa Fuson (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:33:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:59
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:07:59
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27NOV2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		28 Dec 2020 07:36:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27NOV2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SAMPLE SHIPPED TO PPD ON 10-DEC-2020 ON ACCESSION NUMBER 1F68068.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:28:26
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 27NOV2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:43:41
User entered '27 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:33:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:33:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 5 is dated 29NOV2020 in EDC, however the same is dated as 10DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 04:44:31
Query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 5 is dated 29NOV2020 in EDC, however the same is dated as 10DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks' answered with 'edc is correct will update with ppd' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:26:18
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample recorded under Illness Visit Day 5 is dated 29NOV2020 in EDC, however the same is dated as 10DEC2020in PPD Central lab. Please review the appropriate date and visit and update accordingly in EDC or in PPD lab via DCF. Thanks' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:29:01
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:08:02
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:08:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		28 Dec 2020 07:36:50
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SAMPLE SHIPPED TO PPD ON 10-DEC-2020 ON ACCESSION NUMBER 1F68068.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:28:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 29NOV2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:43:50
User entered '29 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:33:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:33:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 20:08:06
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	11 Dec 2020 18:48:22
	(b) (4)	

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:08:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		28 Dec 2020 07:36:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SAMPLE SHIPPED TO PPD ON 10-DEC-2020 ON ACCESSION NUMBER 1F68068.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:28:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01DEC2020 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:43:58
User entered '01 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:33:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:33:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:08:16
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:08:16
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03DEC2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		28 Dec 2020 07:36:55
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03DEC2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SAMPLE SHIPPED TO PPD ON 10-DEC-2020 ON ACCESSION NUMBER 1F68068.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:29:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03DEC2020 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:44:06
User entered '03 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:33:31

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:51:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SAMPLE SHIPPED TO PPD ON 10-DEC-2020 ON ACCESSION NUMBER 1F68068.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:29:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 08DEC2020 is recorded under Illness Visit Day 14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 10:44:16
User accepted default value 'Day 14 (Day 14)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:33:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 05:00:28
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 20:09:29
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Hello this is incorrect. this is what day the site scanned it into preclarus. however, it was collected on 08-dec-2020' (Site from DM).	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:58:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 07:23:15
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:09:29
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 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 appropriate visit. Else clarify, thank you. ' (Site from DM).		28 Dec 2020 06:51:16
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 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 appropriate visit. Else clarify, thank you. ' answered with 'SAMPLE SHIPPED TO PPD ON 10-DEC-2020 ON ACCESSION NUMBER 1F68068.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:29:27
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 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 appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:51:02
User entered '08 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:33:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:33:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 20:09:33
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 14:30:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 14:30:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 14:30:50
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 18:48:22
User entered empty.	Melissa Fuson (b) (4)	11 Dec 2020 18:48:22
	(b) (4)	

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:09:33
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		21 Jan 2021 13:27:42
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED SALIVA COLLECTION LOG WITH PAPERWORK HERE AT SITE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:25:15
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10DEC2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:43:26
User entered '15 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:30:50
User entered empty.	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:33:31

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:33:31

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	11 Feb 2021 20:09:36
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Dec 2020 14:33:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Dec 2020 14:33:23
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Dec 2020 14:33:23
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Dec 2020 18:48:22
User entered empty.	Melissa Fuson (b) (4)	11 Dec 2020 18:48:22
	(b) (4)	

US3412224

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:09:36
User entered empty.	Melissa Fuson (b) (4) (b) (4)	11 Dec 2020 18:48:22

US3412224

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:33
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:05:28

US3412224

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:33
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:05:28

US3412224

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[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 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:41:33
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:05:28

US3412224

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'SICKD1'	System	02 Dec 2020 20:05:28

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '09:54'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered '25 Nov 2020 09:54'	System	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '166.4' cm	Melissa Fuson (b) (4)	02 Dec 2020 20:07:04
DataPoint set to visible.	(b) (4) System	02 Dec 2020 20:05:28

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '84.8' kg	Melissa Fuson (b) (4)	02 Dec 2020 20:07:04
DataPoint set to visible.	(b) (4) System	02 Dec 2020 20:05:28

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '36.8' C	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '64'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'bpm'	System	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '14'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'breaths/min'	System	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '122'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'mmHg'	System	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:26
User entered '94'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User entered 'mmHg'	System	02 Dec 2020 20:07:04

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27

US3412224

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27

US3412224

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:44
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:27

US3412224

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:44
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:27

US3412224

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:33:31

[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 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:52
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:45

US3412224

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:42:52
User entered '25 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	02 Dec 2020 20:07:45

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:41
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:34

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:34

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:34

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	10 Feb 2021 14:59:34

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered 'No (N)'	Steven Anderson (b) (4)	10 Feb 2021 14:59:40
	(b) (4)	

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:50
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Feb 2021 14:59:40

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:54
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:46

US3412224

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:54
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:46

US3412224

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:33:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:58
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:52

US3412224

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:33:31

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:45:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 20:04:58
User entered empty.	Steven Anderson (b) (4) (b) (4)	10 Feb 2021 14:59:52

US3412224

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:15
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:41

US3412224

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:15
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:41

US3412224

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:15
User entered 'Clinic (Clinic)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:41

US3412224

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

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 20:44:41

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 00:40:55
DataPoint Un-verified.	Andrea Newlands (b) (4)	12 Apr 2021 15:24:41
User entered '30 Dec 2020' reason for change: Data Entry Error	(b) (4)	12 Apr 2021 15:24:41
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:44:31
User entered '12 Jan 2021'	Mason Urban (b) (4)	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:27:35

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:31
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:27:35

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
User closed query 'Per IRT, subject was unblinded on 30DEC2020. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 03:18:08
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:40:55
Query 'Per IRT, subject was unblinded on 30DEC2020. Please review and reconcile. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:24:45
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:24:41
User entered '30 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:24:41
User opened query 'Per IRT, subject was unblinded on 30DEC2020. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:05:11
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:44:31
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:31
User entered 'Placebo (Placebo)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:31
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 11:49:10
User entered 'Placebo (Placebo)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:31
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 11:49:10
User entered 'Placebo (Placebo)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:44:31
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '1'	System	13 Jan 2021 20:44:55

US3412224

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

Form: Unblinding

Generated On: 11 Aug 2021 22:33:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'I'	System	13 Jan 2021 20:44:55

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '166' cm	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '90.7' kg	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '32.91479'	System	13 Jan 2021 20:46:51
DataPoint set to visible.	System	13 Jan 2021 20:44:55

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '166' cm	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '90.7' kg	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '32.91479'	System	13 Jan 2021 20:46:51
DataPoint set to visible.	System	13 Jan 2021 20:44:55

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User accepted default value 'Pre-Dose (PREDOSE)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '15:31'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '12 Jan 2021 15:31'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '36.5' C	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered 'Oral (Oral)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered empty.	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '56'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'bpm'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '10'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'breaths/min'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Jan 2021 20:47:09
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	13 Jan 2021 20:47:09
User entered '122' reason for change: Data Entry Error	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:09
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Jan 2021 20:46:51
User entered '12'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User closed query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	13 Jan 2021 20:47:09
Query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' answered by data change (Site from System).	System	13 Jan 2021 20:47:09
User opened query 'Diastolic blood pressure is greater than Systolic blood pressure. Please correct.' (Site from System).	System	13 Jan 2021 20:46:51
User entered '80'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '166' cm	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '90.7' kg	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:33:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '32.91479'	System	13 Jan 2021 20:46:51
DataPoint set to visible.	System	13 Jan 2021 20:44:55

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User accepted default value 'Post-Dose (POSTDOSE)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '16:15'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '12 Jan 2021 16:15'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '97.8' F	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered 'Oral (Oral)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered empty.	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '59'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'bpm'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '14'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'breaths/min'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '106'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:47:17
User entered '70'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:46:51

US3412224

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	13 Jan 2021 20:46:51

US3412224

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:20
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:26

US3412224

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:20
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:26

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:05
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:05
User entered empty.	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:05
User entered empty.	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mRNA-1273'	System	13 Jan 2021 20:47:41
DataPoint set to visible.	System	13 Jan 2021 20:44:55

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:05
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:05
User entered '15:45'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '12 Jan 2021 15:45'	System	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:05
User entered 'Left Arm (LEFT ARM)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.		13 Mar 2021 16:48:05
User entered 'ONCE'	System	13 Jan 2021 20:47:41

US3412224

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

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 20:47:41

US3412224

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:45:08
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:45:12

US3412224

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:45:08
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:45:12

US3412224

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:45:08
User entered '15:35'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:45:12

US3412224

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '12 Jan 2021 15:35'	System	13 Jan 2021 20:45:12

US3412224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:45:13
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:45:24

US3412224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:45:13
User entered '12 Jan 2021'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:45:24

US3412224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:45:13
User entered '15:32'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:45:24

US3412224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:33:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '12 Jan 2021 15:32'	System	13 Jan 2021 20:45:24

US3412224

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

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:48:28
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Jan 2021 20:45:29

US3412224

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

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '1'	System	13 Jan 2021 20:45:29

US3412224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:54:01
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 17:16:19

US3412224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
Query 'please enter OL-D29 visit CRFs from 9 Feb 2021' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:37:59
DataPoint Verified.		13 Mar 2021 16:54:01
User opened query 'please enter OL-D29 visit CRFs from 9 Feb 2021' (Site from CRA).		10 Mar 2021 19:22:13
User entered '19 Jan 2021'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 17:16:19

US3412224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:54:01
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	19 Jan 2021 17:16:19

US3412224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:54:01
User entered empty.	Mason Urban (b) (4) (b) (4)	19 Jan 2021 17:16:19

US3412224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:54:07
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
User entered 'Yes (Y)'	(b) (4) Mason Urban (b) (4) (b) (4)	19 Jan 2021 17:16:28

US3412224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'I'	System	19 Jan 2021 17:16:28

US3412224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '1'	System	19 Jan 2021 17:16:28
DataPoint set to visible.	System	19 Jan 2021 17:16:28

US3412224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:54:13
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:14

US3412224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:54:13
User entered '09 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:14

US3412224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:54:13
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:14

US3412224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'OLD29'	System	12 Mar 2021 14:01:14

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Newlands (b) (4)	12 Mar 2021 14:01:48
	(b) (4)	

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '09 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '10:22'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '09 Feb 2021 10:22'	System	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '36.6' C	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered 'Oral (Oral)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '58'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'bpm'	System	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '16'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'breaths/min'	System	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '112'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '74'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	12 Mar 2021 14:01:48

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User accepted default value 'Post-Dose (POSTDOSE)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '09 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '11:38'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '09 Feb 2021 11:38'	System	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '97.7' F	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered 'Oral (Oral)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '64'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'bpm'	System	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '14'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'breaths/min'	System	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '118'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:14
User entered '78'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	12 Mar 2021 14:02:26

US3412224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:57
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:03:19

US3412224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:57
User entered '09 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:03:19

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

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)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mRNA-1273'	System	12 Mar 2021 14:07:25
DataPoint set to visible.	System	19 Jan 2021 17:16:28

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:38
User entered '09 Feb 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:38
User entered '11:06'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '09 Feb 2021 11:06'	System	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:38
User entered 'Left Arm (LEFT ARM)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.		13 Mar 2021 16:55:38
User entered 'ONCE'	System	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:33:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'INTRAMUSCULAR'	System	12 Mar 2021 14:07:25

US3412224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:55:43
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 20:47:45

US3412224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'I'	System	16 Feb 2021 20:47:45

US3412224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:56:18
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Feb 2021 15:51:25

US3412224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:56:18
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
User entered '16 Feb 2021'	Mason Urban (b) (4)	17 Feb 2021 15:51:25

US3412224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:56:18
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	17 Feb 2021 15:51:25

US3412224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:33:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:56:18
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
User entered empty.	Mason Urban (b) (4)	17 Feb 2021 15:51:25

US3412224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 16:56:22
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:37:04
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Feb 2021 15:51:30

US3412224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:33:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'I'	System	17 Feb 2021 15:51:30

US3412224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:56:59
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:25

US3412224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:56:59
User entered '09 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:25

US3412224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:56:59
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:25

US3412224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:33:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'OLD57'	System	12 Mar 2021 14:25:25

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered '09 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered '15:20'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '09 Mar 2021 15:20'	System	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered '36.5' C	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered 'Oral (Oral)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered '66'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'bpm'	System	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered '16'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'breaths/min'	System	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered '122'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:19
User entered '90'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered 'mmHg'	System	12 Mar 2021 14:25:45

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22

US3412224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:33:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22

US3412224

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:31
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:56

US3412224

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:33:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:31
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:25:56

US3412224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:44
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:26:05

US3412224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:44
User entered '09 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:26:05

US3412224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 16:57:44
User entered '15:36'	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:26:05

US3412224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:33:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:02:22
User entered '09 Mar 2021 15:36'	System	12 Mar 2021 14:26:05

US3412224

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:33:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:16
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:36:31
User closed query 'Please complete COVID Assessment and Illness Visit folders for symptoms starting on 23 Nov 2020 per source ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:24:46
Query 'Please complete COVID Assessment and Illness Visit folders for symptoms starting on 23 Nov 2020 per source ' answered with 'Have been completed as of 04-dec-2020' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	04 Dec 2020 15:03:18
User opened query 'Please complete COVID Assessment and Illness Visit folders for symptoms starting on 23 Nov 2020 per source ' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 20:21:37
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:23:54
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:34:46

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Localised infection, LLT: Infected finger - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:34:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:34:41
Data point term sent to Coder	System	11 Sep 2020 12:37:45
User entered 'Infected Right Index Finger'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:24
DataPoint Un-verified.		19 Oct 2020 16:14:10
DataPoint Verified.		19 Oct 2020 16:14:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:26
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:30
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:38
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).		12 Sep 2020 16:05:19
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	11 Sep 2020 13:52:30
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:43
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User entered empty.	System	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:46
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 20:44:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:47
User entered '08 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 20:44:38
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:51
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User entered empty.	System	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:14:57
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:02
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:04
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:10
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		14 Sep 2020 10:56:59
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered with 'no' (Site from System).	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:37:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Sep 2020 12:36:52
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:15:15
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:15:19
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:21
User closed query 'CDM RQ: Per previous query, 'Admitted to ICU?' is recorded as NO, however, if the patient was not hospitalised, response to 'Admitted to ICU?' should be left blank. Please review and update as appropriate.' (Site from DM).		16 Oct 2020 05:03:15
Query 'CDM RQ: Per previous query, 'Admitted to ICU?' is recorded as NO, however, if the patient was not hospitalised, response to 'Admitted to ICU?' should be left blank. Please review and update as appropriate.' answered with 'subject was not admitted to ICU coordinator took off answer' (Site from DM).	Steven Anderson (b) (4) (b) (4)	07 Oct 2020 16:06:52
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	07 Oct 2020 16:06:31
User opened query 'CDM RQ: Per previous query, 'Admitted to ICU?' is recorded as NO, however, if the patient was not hospitalised, response to 'Admitted to ICU?' should be left blank. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:33:44
User closed query 'Per CDM: Please confirm if AE required hospitalisation and if not, remove response from 'Admitted to ICU?' as this is not required unless patient was hospitalised.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:33:44
Query 'Per CDM: Please confirm if AE required hospitalisation and if not, remove response from 'Admitted to ICU?' as this is not required unless patient was hospitalised.' answered with 'HAD WENT TO SEE HER PRIMARY CARE PHYSICIAN' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:21:25
User opened query 'Per CDM: Please confirm if AE required hospitalisation and if not, remove response from 'Admitted to ICU?' as this is not required unless patient was hospitalised.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:58:22
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:37
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:39
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:40
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:42
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:46
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:48
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:15:50
User entered 'None (NONE)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:16:06
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 05:36:42
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'UPDATED CON MEDS WITH CLINDAMYCIN' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:25:00
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:09:57
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:16:08
User entered 'I'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:16:19
User entered '0'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:16:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:44:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:16:22
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:16:26
User entered empty.	Mylene Asmar-Rios (b) (4)	11 Sep 2020 12:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User entered '0'	System	11 Sep 2020 12:36:52

US3412224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User entered '1'	System	11 Sep 2020 12:36:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:33:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:24
User entered '0'	System	11 Sep 2020 12:36:52

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
Reviewed for Safety.		29 Dec 2020 17:39:10
User entered	System	29 Dec 2020 17:38:48
'USA-US061-2020-mRNA-1273-P301000020'		
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 17:38:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 03:50:09
User closed query 'Per CRF Guidelines term is to be entered as Symptomatic COVID 19 - please re-correct source and update this term in eDC' (Site from CRA).		24 Feb 2021 03:50:04
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 19:15:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 19:15:03
Data point term sent to Coder	System	17 Feb 2021 19:13:36
Query 'Per CRF Guidelines term is to be entered as Symptomatic COVID 19 - please re-correct source and update this term in eDC' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 19:13:25
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 19:12:52
User entered 'symptomatic COVID-19' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 19:12:52
User opened query 'Per CRF Guidelines term is to be entered as Symptomatic COVID 19 - please re-correct source and update this term in eDC' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 13:24:04
User closed query 'Please change AE term to " Symptomatic Covid-19 " without quotation marks' (Site from CRA).		03 Feb 2021 13:24:04
Query 'Please change AE term to " Symptomatic Covid-19 " without quotation marks' answered with 'SOURCE HAS SYMPTOMATIC COVID-19 CROSSED OUT AND JUST HAS COVID-19' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Jan 2021 19:55:46
User opened query 'Please change AE term to " Symptomatic Covid-19 " without quotation marks' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 21:13:26
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Dec 2020 14:36:44

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:36:44 23 Dec 2020 14:36:09 23 Dec 2020 14:35:24
User entered 'COVID-19' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:35:24
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:27:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Steven Anderson (b) (4) (b) (4)	10 Dec 2020 19:27:53 10 Dec 2020 19:26:52 10 Dec 2020 19:26:23
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Dec 2020 19:26:23
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 17:20:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	02 Dec 2020 17:20:50 02 Dec 2020 17:19:29
User entered 'upper respiratory infection'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:57:04
User closed query 'please update to YEs since illness visit and daily telehealth contacts' (Site from CRA).		19 Mar 2021 15:57:00
Query 'please update to YEs since illness visit and daily telehealth contacts' answered with 'updated' (Site from CRA).		16 Mar 2021 19:35:59
User entered 'Yes (Y)' reason for change: Data Entry Error		16 Mar 2021 19:35:49
DataPoint Un-verified.		13 Mar 2021 17:07:41
DataPoint Verified.		13 Mar 2021 17:07:35
User opened query 'please update to YEs since illness visit and daily telehealth contacts' (Site from CRA).		13 Mar 2021 17:06:24
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:06:33
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:06:49
User closed query 'Per CDM: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is NO, however Covid Diagnostic Test page dated 25NOV2020 records 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' as YES. Please review and reconcile.' (Site from DM).		28 Dec 2020 06:07:06
Query 'Per CDM: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is NO, however Covid Diagnostic Test page dated 25NOV2020 records 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' as YES. Please review and reconcile.' answered with 'UPDATED AE TO REFLECT SUBJECT TESTED POSTIVE - CHANGED NO TO YES' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:34:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 14:34:26
User opened query 'Per CDM: 'Is this event a confirmed diagnosis of Symptomatic Covid-19?' is NO, however Covid Diagnostic Test page dated 25NOV2020 records 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' as YES. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 11:14:19
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:09
User entered '23 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:13
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:16
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Dec 2020 19:26:23
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:18
User entered '08 Dec 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Dec 2020 19:26:23
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:21
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Severity

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
User closed query 'Please clarify that per PI AE is mild, despite mild to moderate symptoms as noted in narrative - please clarify narrative if to remain mild' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 11:58:41
DataPoint Verified.		15 Apr 2021 11:58:40
Query 'Please clarify that per PI AE is mild, despite mild to moderate symptoms as noted in narrative - please clarify narrative if to remain mild' answered with 'This has been clarified as mild, grade 1' (Site from CRA).		- 09 Apr 2021 12:33:28
User opened query 'Please clarify that per PI AE is mild, despite mild to moderate symptoms as noted in narrative - please clarify narrative if to remain mild' (Site from CRA).		25 Mar 2021 19:35:49
User closed query 'please confirm severity. Per source note mild to moderate - should this be changed to moderate?' (Site from CRA).		25 Mar 2021 19:35:49
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 13:11:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 13:10:45
Query 'please confirm severity. Per source note mild to moderate - should this be changed to moderate?' answered with 'per sub I this is correct' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 19:40:57
User opened query 'please confirm severity. Per source note mild to moderate - should this be changed to moderate?' (Site from CRA).		13 Mar 2021 17:13:31
DataPoint Un-verified.		13 Mar 2021 17:12:48
DataPoint Verified.		13 Mar 2021 17:07:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:24
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:29
User entered '0'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered '0'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered '0'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered '0'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered '0'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered 'Not Applicable (NOT APPLICABLE)'	Melissa Fuson (b) (4)	23 Dec 2020 14:35:53
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Folder: Adverse Events

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Generated On: 11 Aug 2021 22:33:31

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered '0'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:42:02
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'ADDED MEDICATION TO CON MED ECRF' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:24:06
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 04:34:49
User entered 'I'	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered '0'	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Steven Anderson (b) (4)	10 Dec 2020 19:26:23
Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:19:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 17:19:39
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Jacob sekinger (b) (4)	02 Dec 2020 17:19:39
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 17:19:28
User entered empty.	Jacob sekinger (b) (4)	02 Dec 2020 17:19:28
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:07:35
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
User closed query 'Per DM CLR: Narrative = SUBJECT TOOK 1 TAB OF SUDAFED 24NOV2020 AND 25 NOV2020. However, this does not correspond to the recorded timeframe in the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 11:40:03
User closed query 'Please add notation that PI/Sub-I confirms overall mild AE despite mild to moderate symptoms per subject' (Site from CRA). Query 'Per DM CLR: Narrative = SUBJECT TOOK 1 TAB OF SUDAFED 24NOV2020 AND 25 NOV2020. However, this does not correspond to the recorded timeframe in the CM eCRF. Please review and reconcile data as appropriate.' answered with 'narrative had been written from source notes, so only 24th and 25th had been known at the time, but has been updated.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 11:59:24
		15 Apr 2021 11:59:20
	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:11:44

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STATED A COUGH, NASAL CONGESTION, AND HEADACHE ON 23-NOV-2020. HER SYMPTOMS WERE MILD. SHE FEELS THEY HAVE WORSENERD AND NOW MILD TO MODERATE. SHE DENIES FEVER, CHILLS, NAUSEA, NAUSEA, VOMITING, AND DIARRHEA. NO PROCEDURES OR CON MEDS WERE ADDED. SUB-I AND PI CONFIRM MILD AE. SUBJECT TOOK 1 TAB BID OF SUDAFED 24NOV2020 AND 25 NOV2020 AND WILL CONTINUE TO TAKE AS NEEDED. SUBJECT TOOK A RAPID RESULTS TEST AT WORK, WHICH RETURNED POSITIVE (30NOV2020). 01DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS. 02DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS BUT IS FEELING OK. 03DEC2020 - SUBJECT FEELS BETTER, STILL HAS SOME MILD SYMPTOMS. 08DEC2020 - SUBJECT IS FEELING BETTER WITH NO SYMPTOMS.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 12 Apr 2021 15:10:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STATED A COUGH, NASAL CONGESTION, AND HEADACHE ON 23-NOV-2020. HER SYMPTOMS WERE MILD. SHE FEELS THEY HAVE WORSENERED AND NOW MILD TO MODERATE. SHE DENIES FEVER, CHILLS, NAUSEA, NAUSEA, VOMITING, AND DIARRHEA. NO PROCEDURES OR CON MEDS WERE ADDED. SUB-I AND PI CONFIRM MILD AE. SUBJECT TOOK 1 TAB OF SUDAFED 24NOV2020 AND 25 NOV2020 and will continue to take as needed. SUBJECT TOOK A RAPID RESULTS TEST AT WORK, WHICH RETURNED POSITIVE (30NOV2020). 01DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS. 02DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS BUT IS FEELING OK. 03DEC2020 - SUBJECT FEELS BETTER, STILL HAS SOME MILD SYMPTOMS. 08DEC2020 - SUBJECT IS FEELING BETTER WITH NO SYMPTOMS.'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:10:15
reason for change: Data Entry Error Query 'Please add notation that PI/Sub-I confirms overall mild AE despite mild to moderate symptoms per subject' answered with 'this has been noted' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 12:37:15
DataPoint Un-verified.		09 Apr 2021 12:36:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STATED A COUGH, NASAL CONGESTION, AND HEADACHE ON 23-NOV-2020. HER SYMPTOMS WERE MILD. SHE FEELS THEY HAVE WORSENERED AND NOW MILD TO MODERATE. SHE DENIES FEVER, CHILLS, NAUSEA, NAUSEA, VOMITING, AND DIARRHEA. NO PROCEDURES OR CON MEDS WERE ADDED. Sub-I and PI confirm mild AE. SUBJECT TOOK 1 TAB OF SUDAFED 24NOV2020 AND 25 NOV2020. SUBJECT TOOK A RAPID RESULTS TEST AT WORK, WHICH RETURNED POSITIVE (30NOV2020). 01DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS. 02DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS BUT IS FEELING OK. 03DEC2020 - SUBJECT FEELS BETTER, STILL HAS SOME MILD SYMPTOMS. 08DEC2020 - SUBJECT IS FEELING BETTER WITH NO SYMPTOMS.' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 12:36:56
User opened query 'Per DM CLR: Narrative = SUBJECT TOOK 1 TAB OF SUDAFED 24NOV2020 AND 25 NOV2020. However, this does not correspond to the recorded timeframe in the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:52:45
User opened query 'Please add notation that PI/Sub-I confirms overall mild AE despite mild to moderate symptoms per subject' (Site from CRA).		25 Mar 2021 19:37:10
User closed query 'Per CDM re-query: The Severity is recorded as Grade 1. Per Narrative = WORSENERED AND NOW MILD TO MODERATE, please review if the Severity should be updated to the grade above baseline for the worsened condition. Please review and update as appropriate else clarify in query response.' (Site from DM).		25 Mar 2021 05:22:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: The Severity is recorded as Grade 1. Per Narrative = WORSENER AND NOW MILD TO MODERATE, please review if the Severity should be updated to the grade above baseline for the worsened condition. Please review and update as appropriate else clarify in query response.' answered with 'severity updated' (Site from DM).	Andrea Newlands (b) (4)	24 Mar 2021 13:10:36
User closed query 'Per DM CLR: Narrative = WORSENER AND NOW MILD TO MODERATE. Please review and determine if the recorded severity should be updated with this information. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 05:00:26
User opened query 'Per CDM re-query: The Severity is recorded as Grade 1. Per Narrative = WORSENER AND NOW MILD TO MODERATE, please review if the Severity should be updated to the grade above baseline for the worsened condition. Please review and update as appropriate else clarify in query response.' (Site from DM).		17 Mar 2021 05:00:23
Query 'Per DM CLR: Narrative = WORSENER AND NOW MILD TO MODERATE. Please review and determine if the recorded severity should be updated with this information. ' answered with 'recorded severity' (Site from DM).		16 Mar 2021 19:39:49
DataPoint Verified.		13 Mar 2021 17:07:35
User opened query 'Per DM CLR: Narrative = WORSENER AND NOW MILD TO MODERATE. Please review and determine if the recorded severity should be updated with this information. ' (Site from DM).		01 Mar 2021 08:29:13
User closed query 'please complete narrative through resolution of symptoms' (Site from CRA).		24 Feb 2021 03:50:30

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STATED A COUGH, NASAL CONGESTION, AND HEADACHE ON 23-NOV-2020. HER SYMPTOMS WERE MILD. SHE FEELS THEY HAVE WORSENERED AND NOW MILD TO MODERATE. SHE DENIES FEVER, CHILLS, NAUSEA, NAUSEA, VOMITING, AND DIARRHEA. NO PROCEDURES OR CON MEDS WERE ADDED. SUBJECT TOOK 1 TAB OF SUDAFED 24NOV2020 AND 25 NOV2020. SUBJECT TOOK A RAPID RESULTS TEST AT WORK, WHICH RETURNED POSITIVE (30NOV2020). 01DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS. 02DEC2020 - SUBJECT STILL EXPERIENCING MILD-MODERATE SYMPTOMS BUT IS FEELING OK. 03DEC2020 - SUBJECT FEELS BETTER, STILL HAS SOME MILD SYMPTOMS. 08DEC2020 - SUBJECT IS FEELING BETTER WITH NO SYMPTOMS.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 19:22:48
Query 'please complete narrative through resolution of symptoms' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	17 Feb 2021 19:22:15

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT STATED A COUGH, NASAL CONGESTION, AND HEADACHE ON 23-NOV-2020. HER SYMPTOMS WERE MILD. SHE FEELS THEY HAVE WORSENERED AND NOW MILD TO MODERATE. SHE DENIES FEVER, CHILLS, NAUSEA, NAUSEA, VOMITING, AND DIARRHEA. NO PROCEDURES OR CON MEDS WERE ADDED. subject took 1 tab of sudafed 24nov2020 and 25 nov2020. Subject took a rapid results test at work, which returned positive (30nov2020). 01Dec2020 - subject still experiencing mild-moderate symptoms 02dec2020 - subject still experiencing mild-moderate symptoms but is feeling ok 03dec2020 - subject feels better, still has some mild symptoms 08Dec2020 - subject is feeling better with no symptoms' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 19:22:08
User opened query 'please complete narrative through resolution of symptoms' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 20:54:31
User entered 'SUBJECT STATED A COUGH, NASAL CONGESTION, AND HEADACHE ON 23-NOV-2020. HER SYMPTOMS WERE MILD. SHE FEELS THEY HAVE WORSENERED AND NOW MILD TO MODERATE. SHE DENIES FEVER, CHILLS, NAUSEA, NAUSEA, VOMITING, AND DIARRHEA. no procedures or con meds were added.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Dec 2020 19:29:11
User entered 'Subject stated a cough, nasal congestion, and headache on 23-Nov-2020. Her symptoms were mild. she feels they have worsened and now mild to moderate. she denies fever, chills, nausea, nausea, vomiting, and diarrhea.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Dec 2020 19:28:55
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:33:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 19:35:49
User entered '0'	System	02 Dec 2020 17:19:28

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User coded data point as SOC: Ear and labyrinth disorders, HLGt: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 20:32:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 20:32:09
Data point term sent to Coder	System	19 Jan 2021 20:31:20
User entered 'VERTIGO'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '5 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User entered empty.	System	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Jan 2021 15:24:38
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	21 Jan 2021 15:24:38
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Jan 2021 20:31:20
User entered '7 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User entered empty.	System	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'None (NONE)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'l'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:24:38
User entered 'Unknown (UNKNOWN)'	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 21:57:27
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User entered '0'	System	19 Jan 2021 20:31:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:43:30
User entered '1'	System	19 Jan 2021 20:31:20

US3412224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:33:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 20:43:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:42:37
User coded data point as SOC: Psychiatric disorders, HLT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 20:49:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 20:49:48
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 20:49:22
User entered 'Attention deficit disorder'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:42:39
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:42:41
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:42:43
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:42:46
User entered '18 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:42:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:42:53
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:42:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:43:05
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:37:59
User closed query 'mild per source? Please confirm and update accordingly' (Site from CRA).		15 Apr 2021 20:36:09
Query 'mild per source? Please confirm and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	12 Apr 2021 15:20:05
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4)	12 Apr 2021 15:19:54
User opened query 'mild per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 19:44:15
DataPoint Un-verified.		25 Mar 2021 19:43:50
DataPoint Verified.		25 Mar 2021 19:43:31
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:44:21
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:44:24
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:44:27
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:44:30
User entered '0'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:44:32
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:44:51
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:44:55
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:44:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:44:59
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:45:02
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:45:05
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:45:11
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:45:13
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:45:15
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:45:20
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 11:40:15
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	Andrea Newlands (b) (4)	12 Apr 2021 15:22:49
DataPoint Verified.	(b) (4), (b) (6)	03 Apr 2021 13:47:09
User entered 'I'	(b) (4), (b) (6) Andrea Newlands (b) (4)	25 Mar 2021 19:45:23 24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:45:36
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 20:49:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:46:41
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:46:44
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:46:49
User entered empty.	Andrea Newlands (b) (4) (b) (4)	24 Mar 2021 20:49:17

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 20:49:17

US3412224

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:33:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 20:49:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:33:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:16
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:22:39
User entered 'Yes (Y)'		19 Aug 2020 19:02:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:23:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:21:15
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:21:15
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:04:22
User entered 'PROPRANOLOL'	(b) (4), (b) (6)	19 Aug 2020 19:04:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:23:38
User entered 'No (N)'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:23:39
User entered 'ESSENTIAL TREMORS'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:23:51
User entered '80'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:23:53
User entered 'mg (mg)'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:23:54
User entered empty.		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:23:56
User entered 'once daily (QD)'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:24:06
User entered empty.		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:24:05
User entered 'Oral (ORAL)'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:24:02
User entered empty.		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:24:01
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:20:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:16
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:04:03
User entered 'UN UNK 2015'	(b) (4), (b) (6)	19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:24:11
User entered '0'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:24:12
User entered 'Yes (Y)'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:24:14
User entered empty.		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:24:16
User entered 'No (N)'		19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:04:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:59:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 21:59:38
Data point term sent to Coder	System	24 Sep 2020 13:11:24
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:10:48
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:10:48
User entered 'FLUOXETINE - PROZAC' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:10:48
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:22
Data point term sent to Coder	System	19 Aug 2020 19:05:27
User entered 'FLUOXETINE'	(b) (4), (b) (6)	19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'DEPRESSION'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '40'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:21:05
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:21
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:04:39
User entered 'UN UNK 2004'	(b) (4), (b) (6)	19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:04:39

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:06:22
Data point term sent to Coder	System	19 Aug 2020 19:05:28
User entered 'TRAZODONE'	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'INSOMNIA'		19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '50 TO 100'		19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'		19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:21:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:25
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:05:15
User entered 'UN UNK 2016'	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:05:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 06:51:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:51:33
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
Data point term sent to Coder	System	19 Aug 2020 19:06:29
User entered 'FOLIC ACID'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Headaches are not listed as Med Hx - please review source and update as appropriate' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:21:51
Query 'Headaches are not listed as Med Hx - please review source and update as appropriate' answered with 'this condition has been added into edc subject suffers from headaches/migraines' (Site from CRA). DataPoint Verified.	Steven Anderson (b) (4) (b) (4) (b) (4), (b) (6)	07 Oct 2020 16:13:21 26 Aug 2020 15:28:22
User opened query 'Headaches are not listed as Med Hx - please review source and update as appropriate' (Site from CRA).		26 Aug 2020 15:28:16
User entered 'HEADACHES'		19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:40
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:40
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:21:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:33
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:05:40
User entered 'UN UNK 2016'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:05:40
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:05:40
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:05:40

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
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: ESTROGENS CONJUGATED, PRODUCTSYNONYM: PREMARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 04:51:48
Data point term sent to Coder	System	20 Oct 2020 13:50:18
Coding entries removed.	Mylene Asmar-Rios	20 Oct 2020 13:49:24
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: ESTROGENS CONJUGATED, PRODUCTSYNONYM: PREMARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 13:25:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 13:25:40
Data point term sent to Coder	System	20 Oct 2020 13:24:53
Coding entries removed.	Mylene Asmar-Rios	20 Oct 2020 13:24:07
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: ESTROGENS CONJUGATED, PRODUCTSYNONYM: PREMARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:47:03

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Steven Anderson (b) (4)	07 Oct 2020 16:47:03 07 Oct 2020 16:42:34 07 Oct 2020 16:42:16
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: ESTROGENS CONJUGATED, PRODUCTSYNONYM: PREMARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 05:33:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	31 Aug 2020 05:33:58 26 Aug 2020 15:28:22
Data point term sent to Coder User entered 'PREMARIN'	System (b) (4), (b) (6)	19 Aug 2020 19:06:30 19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 11:45:35
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' answered with 'ADDED POST MENOPAUSAL TO MEDICAL HISTORY' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:16:16
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match.. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:03:57
DataPoint Verified.		18 Nov 2020 15:24:40
User closed query 'Per CDM: Previous query response indicates, "updated", however, 'POST MENOPAUSE' is not recorded on the Medical History form. Please clarify and update as appropriate.' (Site from DM).		22 Oct 2020 05:45:22
User entered 'HORMONE REPLACEMENT FOR HYSTERECTOMY' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:49:24
Query 'Per CDM: Previous query response indicates, "updated", however, 'POST MENOPAUSE' is not recorded on the Medical History form. Please clarify and update as appropriate.' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:24:14
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:24:07
User entered 'POST MENOPAUSAL' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:24:07

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:19:09
User opened query 'Per CDM: Previous query response indicates, "updated", however, 'POST MENOPAUSE' is not recorded on the Medical History form. Please clarify and update as appropriate.' (Site from DM).		13 Oct 2020 14:33:13
User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being treated. Please update CM Indication and MH eCRF so there is an appropriate match.' (Site from DM).		13 Oct 2020 14:33:13
Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being treated. Please update CM Indication and MH eCRF so there is an appropriate match.' answered with 'updated' (Site from DM).	Steven Anderson (b) (4)	07 Oct 2020 16:42:21
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	07 Oct 2020 16:42:16
User entered 'Post menopause' reason for change:	Steven Anderson (b) (4)	07 Oct 2020 16:42:16
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being treated. Please update CM Indication and MH eCRF so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:38:12
DataPoint Verified.		26 Aug 2020 15:28:22
User entered 'HORMONE REPLACEMENT'		19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '.625'		19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'		19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:21:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:36
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:06:12
User entered 'UN UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'		19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:06:12

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: GALCANEZUMAB, PRODUCTSYNONYM: EMGALITY [GALCANEZUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:08:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:08:29
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:07:36
User entered 'EMGALITY'	(b) (4), (b) (6)	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:31:45
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'this condition has been added into edc subject suffers from headaches/migraines' (Site from DM).	Steven Anderson (b) (4) (b) (4)	07 Oct 2020 16:13:37
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:38:46
DataPoint Verified.		26 Aug 2020 15:28:22
User entered 'MIGRAINES'		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '20'		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'MG/ML'		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'every month (QM)'	(b) (4), (b) (6)	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:07:15
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:22:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:41
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:07:15
User entered 'UN May 2020'	(b) (4), (b) (6)	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	19 Aug 2020 19:07:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:09:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:09:21
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:08:37
User entered 'PHENTERMINE'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:31:13
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'overweight has been added to subjects medical history. this medication is being used for weight loss for being overweight' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:05:50
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:39:23
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'WEIGHT LOSS'		19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '37.5'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:22:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:47
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:07:46
User entered 'UN Jan 2020'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:07:46
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:07:46

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: RANITIDINE HYDROCHLORIDE, PRODUCTSYNONYM: ZANTAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:09:21
Data point term sent to Coder	System	19 Aug 2020 19:08:39
User entered 'ZANTAC'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '150'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:22:35
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 19:17:52
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:08:15
User entered 'UN UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:40:47
DataPoint Un-verified.	Andrea Newlands (b) (4)	12 Mar 2021 14:34:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	12 Mar 2021 14:34:10
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'		19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:40:49
DataPoint Un-verified.	Andrea Newlands (b) (4)	12 Mar 2021 14:34:10
User entered '09 Jan 2021' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	12 Mar 2021 14:34:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.		19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User entered empty.	System	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User entered empty.	System	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:09:13
User entered empty.	System	19 Aug 2020 19:08:15

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: IBANDRONATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 07:36:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 07:36:43
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:09:42
User entered 'IBANDRONATE SODIUM'	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'OSTEOPOROSIS'		19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '150'	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:08:52
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:52
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:23:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:17:56
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:08:52
User entered 'UN UNK 2008'	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'		19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:08:52
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:08:52
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:08:52

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 22:47:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 22:47:08
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:09:43
User entered 'BACLOFEN'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:31:30
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'this condition has been added into edc subject suffers from headaches/migraines' (Site from DM).	Steven Anderson (b) (4) (b) (4)	07 Oct 2020 16:13:52
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:39:49
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'MIGRAINES'		19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '10'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'three times daily (TID)'	(b) (4), (b) (6)	19 Aug 2020 19:09:23
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:23
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:24:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:18:00
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:09:23
User entered 'UN UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:09:23
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:09:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:11:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:11:27
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:10:43
User entered 'MAGNESIUM'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:25:14
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:20:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:20:12
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'GENERAL HEALTH'		19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '500'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:24:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 19:18:05
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:09:50
User entered 'UN UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:09:50
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:09:50

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	12 Oct 2020 19:24:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 19:24:26
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: CO Q-10 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:11:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:11:27
Data point term sent to Coder	System	19 Aug 2020 19:10:44
User entered 'CO-Q-10'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:25:20
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:20:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:20:42
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '400'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:10:16
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:24:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:18:09
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:10:16
User entered 'UN UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:10:16
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:10:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: RIBOFLAVIN, PRODUCTSYNONYM: VITAMIN B 2 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 08:43:21
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 08:43:21
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:11:48
User entered 'VITAMIN B-2'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:27:17
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Headache migraines has been added into med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:31:52
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:40:11
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'HEADACHES'		19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered '100'	(b) (4), (b) (6)	19 Aug 2020 19:10:51
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:51
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:25:22
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 19:18:14
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:10:51
User entered 'UN UNK 2012'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:10:51
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:10:51
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:10:51

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:12:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:12:31
Data point term sent to Coder	System	19 Aug 2020 19:11:50
User entered 'ALLEGRA'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'SEASONAL ALLERGIES'		19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '180'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:23
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:23
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:25:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:18:18
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:11:23
User entered 'UN UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:11:23
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:11:23

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:12:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:12:31
Data point term sent to Coder	System	19 Aug 2020 19:11:51
User entered 'MELATONIN'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'INSOMNIA'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '3'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:25:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:18:22
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:11:48
User entered 'UN UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'		19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'		19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:11:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:15:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:15:26
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:12:52
User entered 'VITAMIN D'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:22:41
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:21:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:21:14
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Please confirm dose - 10000 mcg is unusual dose - please confirm both dose and units and update accordingly' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:22:16
Query 'Please confirm dose - 10000 mcg is unusual dose - please confirm both dose and units and update accordingly' answered with 'this has been updated to IU in both source and edc' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 16:19:09
User opened query 'Please confirm dose - 10000 mcg is unusual dose - please confirm both dose and units and update accordingly' (Site from CRA). DataPoint Verified.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:31:24
User entered '10000'	(b) (4), (b) (6)	26 Aug 2020 16:15:42
		26 Aug 2020 16:15:38
		26 Aug 2020 15:28:22
		19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'IU (IU)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 17:31:03
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 16:15:40
DataPoint Verified.		26 Aug 2020 15:28:22
User entered 'ug (ug)'		19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:26:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:18:26
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:12:20
User entered 'UN UNK 2004'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:20
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:12:20
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:12:20

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: PYRIDOXINE HYDROCHLORIDE, PRODUCTSYNONYM: VITAMIN B6 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 08:42:09
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 08:42:09
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:12:55
User entered 'VITAMIN B-6'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:22:55
User closed query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify. ' (Site from DM).		22 Oct 2020 05:50:28
Query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify. ' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:24:49
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:24:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:24:40
User opened query 'Per CDM: Prophylaxis is No; however, indication recorded may indicate medication was given as a prophylaxis. Please clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:30:23
DataPoint Verified.		26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:48
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Start date = 2018 per source? Please review and update accordingly' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:23:04
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:19:09
Query 'Start date = 2018 per source? Please review and update accordingly' answered with 'this has been updated to 2018 which was the date written in source' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:33:28
User entered 'UN UNK 2018' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:33:10
User opened query 'Start date = 2018 per source? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 16:17:02
DataPoint Un-verified.	(b) (4), (b) (6)	26 Aug 2020 16:16:16
DataPoint Verified.		26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:26:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 19:18:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:12:48
User entered 'UN UNK 2019'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:12:48
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:12:48

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:14:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:14:23
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:13:58
User entered 'VITAMIN C'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:25:48
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:21:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:21:36
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'GENERAL HEALTH'		19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '1000'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:19
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:19
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:26:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:18:34
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:13:19
User entered 'UN UNK 2019'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:13:19

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
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)	19 Aug 2020 19:14:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 19:14:23
Data point term sent to Coder	System	19 Aug 2020 19:13:58
User entered 'ASPIRIN'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:40:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	29 Oct 2020 20:21:45
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Oct 2020 20:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'		19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'GENERAL HEALTH'		19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '81'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:26:42
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	19 Aug 2020 19:18:39
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:13:45
User entered 'UN UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:13:45
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:13:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: COLLAGEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:16:23
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Aug 2020 19:16:23
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:15:02
User entered 'COLLAGEN'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:27:11
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:21:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:21:56
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'GENERAL HEALTH'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:26:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 19:18:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:14:11
User entered 'UN UNK 2019'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:14:11

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:13:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:13:21
Data point term sent to Coder	System	19 Aug 2020 19:15:03
User entered 'SEMATRIPTAN INJECTION'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:30:12
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'migraine headaches have been put into med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:34:10
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:40:39
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'MIGRAINES'		19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '6'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:27:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'		19 Aug 2020 19:18:49
answered with 'NA' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:14:44
User entered 'UN UNK 2015'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:14:44
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:14:44

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: RIZATRIPTAN BENZOATE, PRODUCTSYNONYM: MAXALT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:17:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:17:27
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:16:04
User entered 'MAXALT'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:27:38
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'Migraine headaches have been added into med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:34:31
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:40:59
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'MIGRAINES'		19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '10'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:16
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:16
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 12:27:17
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 19:18:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:15:16
User entered 'UN UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:15:16
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:15:16

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:17:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:17:26
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:16:07
User entered 'IBUPROFEN'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:28:05
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'migraine headaches have been added into med history' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 17:34:49
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:41:25
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'HEADACHES'		19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '600-800'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:45
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per CDM: Please clarify Start date, since it is prior to the Start Date of the corresponding Medical History (UN UNK 2010), and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 06:12:53
Query 'Per CDM: Please clarify Start date, since it is prior to the Start Date of the corresponding Medical History (UN UNK 2010), and update as appropriate.' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:26:07
User opened query 'Per CDM: Please clarify Start date, since it is prior to the Start Date of the corresponding Medical History (UN UNK 2010), and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 14:29:57
DataPoint Verified.		26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:27:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).		19 Aug 2020 19:19:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:15:45
User entered 'UN UNK 2000'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:15:45
	(b) (4), (b) (6)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:15:45

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:17:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 19:17:28
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 19:17:09
User entered 'FLUTICASONE'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'SEASONAL ALLERGIES'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 14:26:21
Query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'actual dosage has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:52:56
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:52:44
User entered '50' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:52:44
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of spray count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:41:55
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '1'		19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:31:19
User closed query 'Per CDM: Dose unit is 'Other-MCG'; However 'ug' is an available pre-defined option equivalent to MCG. Please update as appropriate' (Site from DM).		22 Oct 2020 05:42:52
Query 'Per CDM: Dose unit is 'Other-MCG'; However 'ug' is an available pre-defined option equivalent to MCG. Please update as appropriate' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:26:43
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:26:35
User entered 'ug (ug)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:26:35
User opened query 'Per CDM: Dose unit is 'Other-MCG'; However 'ug' is an available pre-defined option equivalent to MCG. Please update as appropriate' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:19:44
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Other (OTHER)'		19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:31:22
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:26:35
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:26:35
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:19:09
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:52:44
User entered 'mcg' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 20:52:44
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'SPRAY EACH NOSTRIL'		19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'twice daily (BID)'		19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:28:22
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		20 Aug 2020 12:27:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 19:19:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 19:16:29
User entered 'UN UNK 2005'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 15:28:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4)	26 Aug 2020 15:28:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 19:16:29

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Please verify and update Flushot to edc to match source. Thank you. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:21:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:30:44
Data point term sent to Coder	System	29 Oct 2020 20:24:00
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:23:36
Query 'Please verify and update Flushot to edc to match source. Thank you. ' answered with 'UPDATED' (Site from CRA).	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:27:19
User opened query 'Please verify and update Flushot to edc to match source. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 16:21:44
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:19:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:56:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:56:51
Data point term sent to Coder	System	24 Sep 2020 13:18:35
User entered 'CLINDAMYCIN' reason for change:	Melissa Fuson (b) (4)	24 Sep 2020 13:18:03
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 13:16:34

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'CLINDAM4CIN'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:21:10
User closed query 'Per DM CLR: Please review Indication and please update to specify the location and type of Infection or update to provide the actual MH or AE term that this medication was used to treat, Please update as appropriate or provide clarification.' (Site from DM).		09 Nov 2020 05:36:17
Query 'Per DM CLR: Please review Indication and please update to specify the location and type of Infection or update to provide the actual MH or AE term that this medication was used to treat, Please update as appropriate or provide clarification.' answered with 'UPDATED TO INFECTION - RIGHT INDEX FINGER PER AE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:24:03
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:23:36
User entered 'INFECTION - RIGHT INDEX FINGER' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 20:23:36
User opened query 'Per DM CLR: Please review Indication and please update to specify the location and type of Infection or update to provide the actual MH or AE term that this medication was used to treat, Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:09:44
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'INFECTION'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered '300'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'three times daily (TID)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered '18 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered '28 Aug 2020'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 16:19:09
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User entered '3'	System	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User entered '1'	System	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:26
User entered '804 (804)'	System	24 Sep 2020 13:16:27

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:31:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:30:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:30:42
Data point term sent to Coder	System	20 Oct 2020 13:29:58
User entered 'FLU SHOT'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:31:41
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:31:45
User entered 'INFLUENZA PROPHYLAXIS'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:25:26
User closed query 'per CRF guidelines please indicate actual dosage (0.5 mL)' (Site from CRA).	(b) (4), (b) (6)	03 Feb 2021 13:25:22
Query 'per CRF guidelines please indicate actual dosage (0.5 mL)' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	02 Dec 2020 17:23:34
User entered '0.5' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 17:23:28
User opened query 'per CRF guidelines please indicate actual dosage (0.5 mL)' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 20:12:19
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:31:48
User entered '1'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:25:25
User entered 'mL (mL)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 17:23:28
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 20:11:45
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:31:50
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:25:29
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 17:23:28
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 20:11:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:31:52
User entered 'INJECTION'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:31:55
User entered 'once (ONCE)'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:31:56
User entered empty.	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:13
User entered 'Intramuscular (INTRAMUSCULAR)'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:15
User entered empty.	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:19
User entered '25 Sep 2020'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:21
User entered '0'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:23
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:25
User entered '25 Sep 2020'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:27
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User entered empty.	System	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User entered empty.	System	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:32
User entered empty.	System	20 Oct 2020 13:29:17

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 07:13:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Apr 2021 07:13:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:16:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Jan 2021 15:23:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Jan 2021 15:23:01
Data point term sent to Coder	System	21 Jan 2021 15:22:02
User entered 'MECLIZINE'	Melissa Fuson (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered 'VERTIGO'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered '25'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered 'once daily (QD)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered '5 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered '0'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered '7 Jan 2021'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:48
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User entered '1'	System	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User entered '1'	System	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:37
User entered '804 (804)'	System	21 Jan 2021 15:21:09

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED 12 HOUR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 15:24:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Jan 2021 15:24:02
Data point term sent to Coder	System	21 Jan 2021 15:23:03
User entered 'SUDAFED 12 HOUR'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered 'URI / COVID-19'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered '120'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered 'twice daily (BID)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered '23 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered '0'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered '28 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:16:16
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User entered '2'	System	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User entered '1'	System	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:12:43
User entered '804 (804)'	System	21 Jan 2021 15:23:02

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 08:49:28
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:15:23
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' answered with 'no worsening, switched from zantac to pepcid, zantac end date updated in edc' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	12 Mar 2021 14:34:43
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 09:00:14
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, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:00:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 21:00:02
Data point term sent to Coder	System	19 Feb 2021 20:59:22
User entered 'pepcid'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered 'GERD'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered '10'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered 'as needed (PRN)' reason for change:	Andrea Newlands (b) (4)	19 Feb 2021 21:02:18
Data Entry Error	(b) (4)	
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	19 Feb 2021 20:59:14
	(b) (4)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered '10 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:22:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:15:23
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:02:18
User entered '2'	System	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:02:18
User entered '1'	System	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:02:18
User entered '804 (804)'	System	19 Feb 2021 20:59:14

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:38:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: ATOMOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: STRATTERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 15:30:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 15:30:47
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 15:22:41
User entered 'strattera'	Andrea Newlands (b) (4)	12 Apr 2021 15:22:26
	(b) (4)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered 'attention deficit disorder'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered '20'	Andrea Newlands (b) (4)	12 Apr 2021 15:22:26
	(b) (4)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	12 Apr 2021 15:22:26
	(b) (4)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered empty.	Andrea Newlands (b) (4)	12 Apr 2021 15:22:26
	(b) (4)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered empty.	Andrea Newlands (b) (4)	12 Apr 2021 15:22:26
	(b) (4)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered '08 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered '0'	Andrea Newlands (b) (4)	12 Apr 2021 15:22:26
	(b) (4)	

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:31:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:38:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 11 Aug 2021 22:33:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 15:22:26

US3412224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:33:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:40:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:32:39
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:56:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:56:38
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	05 Nov 2020 16:56:38
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:56:05
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	05 Nov 2020 16:56:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	05 Nov 2020 16:49:04
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 19:02:50

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered		
'USA-US061-2020-MRNA-1273-P301000020'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.		29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.		29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.		29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.		29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.		29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.		29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.		29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Richard'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gregory'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Powell'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gottschlich'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '4260 Glendale Milford Road'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Cincinnati'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
User entered 'OH'	System	25 Mar 2021 15:52:26

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '45242'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:53:38
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
User entered 'US'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 15:52:26
User entered '2'	System	17 Mar 2021 22:09:07
User entered '1'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'USA-US061-2020-MRNA-1273-P301000020'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Richard'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gregory'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Powell'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gottschlich'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '4260 Glendale Milford Road'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Cincinnati'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
User entered 'OH'	System	25 Mar 2021 15:52:26

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '45242'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:53:38
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
User entered 'US'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 15:52:26
User entered '2'	System	17 Mar 2021 22:09:07
User entered '1'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:33:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
User entered '29/Dec/2020 17:39'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:33:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 15:53:38
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'USA-US061-2020-MRNA-1273-P301000020'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Richard'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gregory'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Powell'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gottschlich'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '4260 Glendale Milford Road'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Cincinnati'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
User entered 'OH'	System	25 Mar 2021 15:52:26

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '45242'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:53:38
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
User entered 'US'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 15:52:26
User entered '2'	System	17 Mar 2021 22:09:07
User entered '1'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:33:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:47:34
User entered '17/Mar/2021 18:09'	System	17 Mar 2021 22:09:07

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:33:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 22:09:07

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered		
'USA-US061-2020-MRNA-1273-P301000020'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'No (N)'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Richard'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gregory'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered 'Powell'	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Gottschlich'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '4260 Glendale Milford Road'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered 'Cincinnati'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
User entered 'OH'	System	25 Mar 2021 15:52:26

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4)	25 Mar 2021 19:47:34
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 15:53:38
Un-reviewed for Safety.	System	25 Mar 2021 15:52:26
DataPoint Un-verified.	System	25 Mar 2021 15:52:26
User entered empty.	System	25 Mar 2021 15:52:26
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 17:13:49
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:39:37
User entered '45242'	System	29 Dec 2020 17:38:48

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 15:53:38
DataPoint Verified.		13 Mar 2021 17:13:49
User entered 'US'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 11 Aug 2021 22:33:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Mar 2021 15:52:26
User entered '2'	System	17 Mar 2021 22:09:07
User entered '1'	System	29 Dec 2020 17:39:44

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:33:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:47:34
User entered '25/Mar/2021 11:52'	System	25 Mar 2021 15:52:26

US3412224

Folder: SAE USA-US061-2020-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:33:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:46:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 19:47:34
Reviewed for Safety.		25 Mar 2021 15:53:38
User entered 'I'		25 Mar 2021 15:52:26