

US3922074 (Prod: Synexus Clinical Research US, Inc. - Dallas)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:39:26

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US3922074

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

[Participant ID](#)

US3922074

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

US3922074

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3922074

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" 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) 22 Feb 2021 20:38:34

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 20:38:34

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 20:38:34

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	HEADACHE
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	OBSTRUCTIVE SLEEP APNEA
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 (7)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	DEGENERATIVE DISC DISEASE L5-S1
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	TORN ACL L KNEE
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	COLON POLYP (BENIGN)
Start date (dd MMM yyyy)	19 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	26 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	LUMBAR FUSION L5-S1
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	ACL RECONSTRUCTION L KNEE
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2002
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2002
Stop Year (derived)	2002

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	COLON POLYPECTOMY (BENIGN)
Start date (dd MMM yyyy)	26 AUG 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	26 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	CERVICAL RADICULOPATHY (NERVE PAIN IN NECK)
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 05 Apr 2021 13:10:19

Generated On: 12 Aug 2021 13:39:26

Condition	DEPRESSION
Start date (dd MMM yyyy)	15 MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:05 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:05
Height (<i>xxx.x</i>)	169.0 cm
Weight (<i>xxx.x</i>)	107.7 kg
BMI (<i>xxx.x</i>)	37.70876 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:38:34

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

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) 22 Feb 2021 20:38:34

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 20:38:34

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What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 111149

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) 22 Feb 2021 20:38:34

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 12:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	15:07 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 15:07
Temperature (xxx.x)	97.5 F
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)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

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.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 14:31 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 14:31

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	2 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:00 (24 HR)
Collection date and time (derived)	2 SEP 2020 13:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:37	2 SEP 2020 13:37
Nasopharyngeal Swab 2	Yes	13:37	2 SEP 2020 13:37

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 15:07

PC Open Date & Time

02 SEP 2020 14:51

PC Close Date & Time

02 SEP 2020 17:21

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 97.8 °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	02 SEP 2020 18:33
PC Open Date & Time	02 SEP 2020 18:16
PC Close Date & Time	03 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

03 SEP 2020 18:31

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

04 SEP 2020 18:32

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 19:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

97.5 °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

07 SEP 2020 18:31

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

08 SEP 2020 17:35

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 15:14

PC Open Date & Time

02 SEP 2020 14:51

PC Close Date & Time

02 SEP 2020 17:21

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

02 SEP 2020 18:34

PC Open Date & Time

02 SEP 2020 18:16

PC Close Date & Time

03 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

03 SEP 2020 18:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

04 SEP 2020 18:32

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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

05 SEP 2020 19:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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

06 SEP 2020 18:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

07 SEP 2020 18:31

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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

08 SEP 2020 17:36

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 15:15
PC Open Date & Time	02 SEP 2020 14:51
PC Close Date & Time	02 SEP 2020 17:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 18:34
PC Open Date & Time	02 SEP 2020 18:16
PC Close Date & Time	03 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 ☒

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

		Yes <input type="checkbox"/>
PC Time stamp	03 SEP 2020 18:32	
PC Open Date & Time	03 SEP 2020 12:00	
PC Close Date & Time	04 SEP 2020 11:59	

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

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EAB) (1725)

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 18:33
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

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)

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

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 ☒

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:32
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

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)

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 17:36
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:31

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 SEP 2020 18:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 SEP 2020 18:31
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3922074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

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)	02 OCT 2020
Time of assessment (00:00-23:59)	11:12 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:12
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

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)	02 OCT 2020
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 13:18
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	26 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3922074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

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) 02 OCT 2020

What was the treatment time? (00:00-23:59) 12:47 (24 HR)

Treatment Date and Time (derived) 02 OCT 2020 12:47

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

US3922074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 OCT 2020

Collection time (00:00-23:59)

11:37 (24 HR)

Collection date and time (derived)

2 OCT 2020 11:37

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Collection date (<i>dd MMM yyyy</i>)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:52	02 OCT 2020 11:52
Nasopharyngeal Swab 2	No		

US3922074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 13:20

PC Open Date & Time

02 OCT 2020 13:07

PC Close Date & Time

02 OCT 2020 15:37

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	02 OCT 2020 18:32
PC Open Date & Time	02 OCT 2020 16:32
PC Close Date & Time	03 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 OCT 2020 18:07
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 OCT 2020 18:32

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 OCT 2020 17:39

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	06 OCT 2020 17:39
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 OCT 2020 17:47

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

08 OCT 2020 17:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 8

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 OCT 2020 17:32

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 9

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

10 OCT 2020 17:37

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 10

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 OCT 2020 17:57

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 11

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	12 OCT 2020 17:34
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 12

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True
PC Time Stamp	13 OCT 2020 17:59
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 13

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	14 OCT 2020 17:36
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 14

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	15 OCT 2020 17:31
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 15

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	16 OCT 2020 16:58
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 16

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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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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

17 OCT 2020 18:06

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 17

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	18 OCT 2020 16:32
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 18

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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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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	19 OCT 2020 16:34
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 19

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 20

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 OCT 2020 18:16

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 21

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	22 OCT 2020 17:31
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 22

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	23 OCT 2020 14:25
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 23

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	24 OCT 2020 20:59
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 24

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 21:15

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 13:21

PC Open Date & Time

02 OCT 2020 13:07

PC Close Date & Time

02 OCT 2020 15:37

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

02 OCT 2020 18:32

PC Open Date & Time

02 OCT 2020 16:32

PC Close Date & Time

03 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

03 OCT 2020 18:08

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

04 OCT 2020 18:33

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

250

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 17:42

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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

06 OCT 2020 17:38

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

07 OCT 2020 17:47

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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

08 OCT 2020 17:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 13:21
PC Open Date & Time	02 OCT 2020 13:07
PC Close Date & Time	02 OCT 2020 15:37

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 18:33
PC Open Date & Time	02 OCT 2020 16:32
PC Close Date & Time	03 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 ☒

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 18:09
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

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 ☒

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 18:33
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 17:42
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

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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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 17:38
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 17:47
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

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 ☒

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 17:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 17:32
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 OCT 2020 17:37
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 OCT 2020 17:57
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
PC Time stamp	12 OCT 2020 17:34
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 OCT 2020 17:59
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 13

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

No ☒

Yes ☐

PC Time stamp

14 OCT 2020 17:36

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 17:31
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	16 OCT 2020 16:58
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 OCT 2020 18:06
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 17
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	18 OCT 2020 16:32
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 OCT 2020 16:34
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 19
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	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 20
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	21 OCT 2020 18:16
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 21
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 17:31
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 22
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 14:25
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 23

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

No ☒

Yes ☐

PC Time stamp

24 OCT 2020 20:59

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 24
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 OCT 2020 21:15
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3922074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

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 _____

US3922074

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments SUBJECT RETURNED CALL

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:38:35

Generated On: 12 Aug 2021 13:39:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:38:35

Generated On: 12 Aug 2021 13:39:26

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) _____

US3922074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:38:35

Generated On: 12 Aug 2021 13:39:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 NOV 2020

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

US3922074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:38:35

Generated On: 12 Aug 2021 13:39:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	04 NOV 2020
Collection time (<i>00:00-23:59</i>)	10:06 (24 HR)
Collection date and time (derived)	04 NOV 2020 10:06

US3922074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:35

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 17:30:58

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

09 NOV 2020 17:30:41

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 17:27:40

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 18:13:33
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 11:23:58
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 09:39:13
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 11:41:49

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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	18 DEC 2020 10:47:01
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 16:34:27

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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	03 JAN 2021 20:52:20
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 JAN 2021 08:56:25
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

15 JAN 2021 00:30:11

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

26 JAN 2021 09:56:20

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 09:24:10
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 17:48:53

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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	13 FEB 2021 15:31:57
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

19 FEB 2021 19:06:30

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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	26 FEB 2021 22:41:49
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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	08 MAR 2021 22:25:20
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 10:47:24
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

19 MAR 2021 08:33:29

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

26 MAR 2021 22:26:09

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

02 APR 2021 14:45:42

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 12:04:32

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 <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	16 APR 2021 09:01:13
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

23 APR 2021 12:36:24

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

30 APR 2021 09:35:11

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 250

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 257

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 271

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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20 JUL 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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27 JUL 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

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03 AUG 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

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10 AUG 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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20 AUG 2021 00:01

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24 AUG 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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31 AUG 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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14 SEP 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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17 SEP 2021 00:01

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21 SEP 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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28 SEP 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 523

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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="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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 733

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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°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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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 ☐

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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="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"/>

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3922074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:39:26

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		02 MAR 2021 00:14:51

US3922074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:34

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Mar 2021 14:15:08

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Mar 2021 14:15:08

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 16:45:14

Generated On: 12 Aug 2021 13:39:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 30 Mar 2021 22:06:29

Generated On: 12 Aug 2021 13:39:26

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) _____

US3922074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 16:45:14

Generated On: 12 Aug 2021 13:39:26

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.

US3922074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 16:45:14

Generated On: 12 Aug 2021 13:39:26

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

Collection date (<i>dd MMM yyyy</i>)	18 MAR 2021
--	-------------

Collection time (<i>00:00-23:59</i>)	10:40 (24 HR)
--	---------------

Collection date and time (derived)	18 MAR 2021 10:40
------------------------------------	-------------------

US3922074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 16:45:14

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 22:11:16

Generated On: 12 Aug 2021 13:39:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922074

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 22:11:16

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922074

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3922074

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:39:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3922074

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

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

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

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

Folder OID	UNBLND_DECIDE
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US3922074

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

Form: Unblinding

Data signed: (b) (4) 11 Mar 2021 16:31:19

Generated On: 12 Aug 2021 13:39:26

Date of updated informed consent (dd MMM yyyy) 22 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 22 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3922074

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

09:49 (24 HR)

Collection date and time (derived)

22 JAN 2021 09:49

US3922074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	10:06
Collection Date and Time (derived)	22 JAN 2021 10:06

US3922074

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 06 Apr 2021 13:36:06

Generated On: 12 Aug 2021 13:39:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

AEID

Adverse event

WORSENING CERVICAL
RADICULOPATHY

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 15:34:03

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

AEID	
Adverse event	WORSENING OF DEPRESSION
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)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 15:34:03

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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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 15:34:03

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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 checked="" 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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

AEID	
Adverse event	PARTIAL HEARING LOSS RIGHT
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)	12 DEC 2020
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) 29 Apr 2021 15:34:03

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

AEID	
Adverse event	TINNITUS RIGHT
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)	12 DEC 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)	19 MAR 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 (5)

Data signed: (b) (4) 29 Apr 2021 15:34:03

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

AEID	
Adverse event	INSOMNIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 29 Apr 2021 15:34:03

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	10 SEP 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"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 29 Apr 2021 15:34:03

Generated On: 12 Aug 2021 13:39:26

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 15:33:32

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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 2013	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication HYDROXYZINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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 (3)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication TESTOSTERONE CYPIONATE

Prophylaxis Yes ☐
No ☒

Indication LOW TESTOSTERONE

Dose per administration 200

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) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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)	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 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 (4)

Data signed: (b) (4) 26 Apr 2021 13:58:45

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Name of Medication INDOMETHACIN

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT HEADACHE

Dose per administration 75

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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 OCT 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMNIA

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 (5)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 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 (6)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

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 (6)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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 2013	
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 (7)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication CERVICAL RADICULOPATHY

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 (7)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CERVICAL RADICULOPATHY

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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)		03 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)		25 NOV 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication ABILIFY

Prophylaxis Yes ☐

No ☒

Indication AE#2 (WORSENING OF DEPRESSION)

Dose per administration 5

Dose unit mg ☒

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☒

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☐

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☒

Topical ☐

Subcutaneous ☐

Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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)	15 DEC 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 (11)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication LATUDA

Prophylaxis Yes ☐
No ☒

Indication AE# 3 BIPOLAR 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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)	20 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)	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) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication AE #4 (RIGHT SIDED PARTIAL
HEARING LOSS) AND AE #5
(RIGHT SIDED TINNITUS)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	Intraocular	<input type="checkbox"/>
	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)		11 JAN 2021
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication LUNESTA

Prophylaxis Yes ☐
No ☒

Indication AE#6 INSOMNIA

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 (13)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication LAMOTRIGINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 200

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) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2014
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) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 250

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)

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

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

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication AE #6 (INSOMNIA)

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)

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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 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"/>

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication ABILIFY

Prophylaxis Yes ☐
No ☒

Indication AE #2 (WORSENING
DEPRESSION)

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	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)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

Name of Medication TRILEPTAL

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR DEPRESSION

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 13:58:45

Generated On: 12 Aug 2021 13:39:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	23 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 20:38:18

Generated On: 12 Aug 2021 13:39:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3922074

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:39:26

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 ☐

Audit

US3922074 (Prod: Synexus Clinical Research US, Inc. - Dallas)

US3922074

Form: Participant Creation

Generated On: 12 Aug 2021 13:39:26

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 18:52:30
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'US3922074'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:29:36

US3922074

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:06:25

US3922074

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:29:37

US3922074

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Clinic (Clinic)'	Michele Reynolds (b) (4)	03 Sep 2020 15:06:25

US3922074

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'SCRN'	System	03 Sep 2020 15:06:25

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:29:38

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '50'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'YEARS'	System	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '50'	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Male (M)'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'I'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:39:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:03

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 07:39:42
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:29:06
User entered '2 Sep 2020'	Chana Hines (b) (4) (b) (4)	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Sep 2020'	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2020'	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Amendment 3 (3)'	Chana Hines (b) (4)	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Chana Hines (b) (4)	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Chana Hines (b) (4)	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Chana Hines (b) (4)	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Chana Hines (b) (4)	02 Sep 2020 20:01:52

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Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 16:29:37

US3922074

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:39:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'I'	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:39:26

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Chana Hines (b) (4)	02 Sep 2020 20:00:33

US3922074

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:39:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:07:31

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 15:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 15:09:46
Data point term sent to Coder	System	03 Sep 2020 15:09:07
User entered 'hypertension'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:06
	(b) (4)	

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2013'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2013'	System	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2013'	System	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:08:06

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 15:09:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 15:09:46
Data point term sent to Coder	System	03 Sep 2020 15:09:08
User entered 'Allergic Rhinitis'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 1996'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 1996'	System	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '1996'	System	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:08:37

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Blood testosterone decreased, LLT: Testosterone low - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 21:31:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 21:31:36
Data point term sent to Coder	System	11 Nov 2020 21:15:36
Coding entries removed.	Pauline Jackson (b) (4)	11 Nov 2020 21:15:12
User entered 'low testosterone' reason for change: Data Entry Error	Pauline Jackson (b) (4)	11 Nov 2020 21:15:12
User coded data point as SOC: Endocrine disorders, HLGT: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Hypogonadism, LLT: Hypogonadism - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 15:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Sep 2020 15:10:47
Data point term sent to Coder	System	03 Sep 2020 15:10:09
User entered 'Hypogonadism'	Michele Reynolds (b) (4)	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2016'	Michele Reynolds (b) (4)	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2016'	System	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2016'	System	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:09:26

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 15:10:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:10:47
Data point term sent to Coder	System	03 Sep 2020 15:10:09
User entered 'Headache'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2019'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2019'	System	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2019'	System	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:10:05

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 15:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:12:41
Data point term sent to Coder	System	03 Sep 2020 15:11:13
User entered 'Heartburn'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2013'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2013'	System	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2013'	System	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:10:29

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 15:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 15:12:41
Data point term sent to Coder	System	03 Sep 2020 15:11:17
User entered 'Obstructive Sleep Apnea'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2008'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2008'	System	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2008'	System	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	03 Sep 2020 15:11:04

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 16:14:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:14:50
Data point term sent to Coder	System	03 Sep 2020 15:12:19
User entered 'Degenerative Disc Disease L5-S1'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2005'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2005'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2005'	System	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2005'	System	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2005'	System	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2005'	System	03 Sep 2020 15:11:57

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 15:35:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 15:35:44
Data point term sent to Coder	System	03 Sep 2020 15:13:21
User entered 'torn ACL L knee'	Michele Reynolds (b) (4)	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2002'	Michele Reynolds (b) (4)	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2002'	Michele Reynolds (b) (4)	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2002'	System	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2002'	System	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2002'	System	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2002'	System	03 Sep 2020 15:12:58

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 15:14:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:14:39
Data point term sent to Coder	System	03 Sep 2020 15:14:22
User entered 'Appendicitis'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 1997'	Michele Reynolds (b) (4)	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 1997'	Michele Reynolds (b) (4)	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 1997'	System	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '1997'	System	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 1997'	System	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '1997'	System	03 Sep 2020 15:13:34

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Benign colonic polyp - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Nov 2020 18:34:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 18:34:29
Data point term sent to Coder	System	04 Nov 2020 18:34:04
Coding entries removed.	Pauline Jackson (b) (4)	04 Nov 2020 18:33:10
User entered 'COLON POLYP (benign)' reason for change: Data Entry Error	(b) (4)	
User entered 'COLON POLYP (benign)' reason for change: Data Entry Error	Pauline Jackson (b) (4)	04 Nov 2020 18:33:10
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 15:14:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 15:14:28
User entered 'Colon Polyp'	Michele Reynolds (b) (4)	03 Sep 2020 15:14:19
	(b) (4)	

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Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #14 COLON POLYPECTOMY done last 26 AUG 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 08:12:20
Query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #14 COLON POLYPECTOMY done last 26 AUG 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' answered with 'spoke to subject for clarification. date updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 16:16:17
User entered '19 Aug 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 16:15:56
User opened query 'Per DM CLR: Please review the start date of this MH as there was a noted procedure of MH #14 COLON POLYPECTOMY done last 26 AUG 2020 that matches this condition. Note that associated conditions usually occur prior the start date of procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 04:12:39
User entered '26 Aug 2020'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '26 Aug 2020'	Michele Reynolds (b) (4)	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Aug 2020'	System	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2020'	System	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Aug 2020'	System	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2020'	System	03 Sep 2020 15:14:19

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion lumbar spine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Sep 2020 14:53:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:53:44
Data point term sent to Coder	System	03 Sep 2020 15:15:31
User entered 'Lumbar fusion L5-S1'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2005'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2005'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2005'	System	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2005'	System	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2005'	System	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2005'	System	03 Sep 2020 15:15:13

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ligament operation, LLT: Anterior cruciate ligament reconstruction - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 20:49:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:49:03
Data point term sent to Coder	System	03 Sep 2020 15:16:33
User entered 'ACL reconstruction L knee'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2002'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2002'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2002'	System	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2002'	System	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2002'	System	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2002'	System	03 Sep 2020 15:15:52

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Sep 2020 15:17:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:17:40
Data point term sent to Coder	System	03 Sep 2020 15:16:36
User entered 'Appendectomy'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 1997'	Michele Reynolds (b) (4)	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 1997'	Michele Reynolds (b) (4)	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 1997'	System	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '1997'	System	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 1997'	System	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '1997'	System	03 Sep 2020 15:16:33

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per DM CLR: Please review and update MH procedure to confirm whether the removed POLYP was benign or cancerous. Ensure associated condition in MH #10 COLON POLYP is updated so there is an appropriate match. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 08:12:27
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Large intestinal polypectomy, LLT: Colon polypectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 08:11:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 08:11:33
Data point term sent to Coder	System	04 Nov 2020 18:33:02
Query 'Per DM CLR: Please review and update MH procedure to confirm whether the removed POLYP was benign or cancerous. Ensure associated condition in MH #10 COLON POLYP is updated so there is an appropriate match. Review and update as appropriate. ' answered with 'condition updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	04 Nov 2020 18:32:47
Coding entries removed.	Pauline Jackson (b) (4) (b) (4)	04 Nov 2020 18:32:40
User entered 'COLON POLYPECTOMY (benign)' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	04 Nov 2020 18:32:40
User opened query 'Per DM CLR: Please review and update MH procedure to confirm whether the removed POLYP was benign or cancerous. Ensure associated condition in MH #10 COLON POLYP is updated so there is an appropriate match. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:11:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Large intestinal polypectomy, LLT: Colon polypectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 15:18:42

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Sep 2020 15:18:42
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 15:17:37
User entered 'Colon polypectomy'	Michele Reynolds (b) (4)	03 Sep 2020 15:17:16
	(b) (4)	

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '26 Aug 2020'	Michele Reynolds (b) (4)	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '26 Aug 2020'	Michele Reynolds (b) (4)	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Aug 2020'	System	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2020'	System	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Aug 2020'	System	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2020'	System	03 Sep 2020 15:17:16

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 11:55:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 11:55:34
Data point term sent to Coder	System	20 Oct 2020 16:24:49
User entered 'cervical radiculopathy (nerve pain in neck)'	lynn yauch (b) (4) (b) (4)	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'un UNK 2019'	lynn yauch (b) (4)	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	lynn yauch (b) (4)	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	lynn yauch (b) (4)	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	lynn yauch (b) (4)	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	lynn yauch (b) (4)	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Jan 2019'	System	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2019'	System	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	20 Oct 2020 16:24:20

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 19:50:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 19:50:49
Data point term sent to Coder	System	02 Apr 2021 19:49:12
User entered 'Depression'	Jennifer Ruiz (b) (4)	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '15 Mar 2020'	Jennifer Ruiz (b) (4)	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'Mar 2020'	System	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2020'	System	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Medical History (16)

Generated On: 12 Aug 2021 13:39:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered empty.	System	02 Apr 2021 19:48:15

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '2 Sep 2020'	Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '12:05'	Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '2 Sep 2020 12:05'	System	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '169.0' cm	Michele Reynolds (b) (4)	03 Sep 2020 15:29:19
DataPoint set to visible.	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '107.7' kg	Michele Reynolds (b) (4)	03 Sep 2020 15:29:19
DataPoint set to visible.	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered '37.70876'	System	03 Sep 2020 15:29:19
DataPoint set to visible.	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'kg/m2'	System	03 Sep 2020 15:29:19
DataPoint set to visible.	System	02 Sep 2020 20:01:52

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:46:24
User entered '98.5' F	(b) (4) Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty; reason for change Data Entry Error	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:46:24
User entered 'Oral (Oral)'	(b) (4) Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:46:24
User entered '76'	(b) (4) Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'bpm'	System	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:46:24
User entered '16'	(b) (4) Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'breaths/min'	System	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:46:24
User entered '131'	(b) (4) Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'mmHg'	System	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:46:24
User entered '78'	(b) (4) Michele Reynolds (b) (4)	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User entered 'mmHg'	System	03 Sep 2020 15:29:19

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:20:34

US3922074

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:20:34

US3922074

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:41:49

US3922074

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '2 Sep 2020'	Michele Reynolds (b) (4)	03 Sep 2020 15:41:49

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

[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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

[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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

[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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

[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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'I'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

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 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '0'	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:39:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:20:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:46:07

US3922074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Chana Hines (b) (4)	02 Sep 2020 20:00:55

US3922074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:49:16
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	16 Nov 2020 15:53:58
User entered '02 Sep 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	12 Nov 2020 15:17:15
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:29:45
User entered '2 Sep 2020'	Chana Hines (b) (4) (b) (4)	02 Sep 2020 20:00:55

US3922074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Clinic (Clinic)'	Chana Hines (b) (4)	02 Sep 2020 20:00:55

US3922074

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'VISIT1'	System	02 Sep 2020 20:00:55

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:59:57

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '111149'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:59:57

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:59:57

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

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)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 05:59:15
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'completed' (Site from DM).	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:48:40
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:48:30
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:41:58

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

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)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:48:30

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:48:30

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:48:30

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Michele Reynolds (b) (4)	03 Sep 2020 15:48:30

US3922074

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:39:26

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	lynn yauch (b) (4)	20 Oct 2020 16:14:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:54:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:54:47

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User accepted default value 'Pre-Dose (PREDOSE)'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50
	(b) (4)	

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:49:41
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' answered with 'updated, however when date selected on calendar, leading zeros not applied' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	12 Nov 2020 15:16:44
User entered '02 Sep 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	12 Nov 2020 15:15:46
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:30:04
User entered '2 Sep 2020'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '12:05'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '02 Sep 2020 12:05'	System	12 Nov 2020 15:15:46
User entered '2 Sep 2020 12:05'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '98.5' F	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Oral (Oral)'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '76'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'bpm'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '16'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'breaths/min'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '131'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'mmHg'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '78'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'mmHg'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:26

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:39:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered missing code ND - Not Done.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User accepted default value 'Post-Dose (POSTDOSE)'	Michele Reynolds (b) (4) (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '2 Sep 2020'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '15:07'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '2 Sep 2020 15:07'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '97.5' F	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Oral (Oral)'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '58'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'bpm'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '13'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'breaths/min'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '140'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'mmHg'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '84'	Michele Reynolds (b) (4)	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'mmHg'	System	03 Sep 2020 15:50:50

US3922074

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)' reason for change: Data Entry Error	Cristina Puig (b) (4)	04 Sep 2020 20:47:26
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 15:51:00

US3922074

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty; reason for change Data Entry Error	Cristina Puig (b) (4)	04 Sep 2020 20:47:26
User entered '2 Sep 2020'	Michele Reynolds (b) (4)	03 Sep 2020 15:51:00

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Chana Hines (b) (4)	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Chana Hines (b) (4)	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

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)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Chana Hines (b) (4)	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 09:24:29
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' answered with 'when selecting date on calendar, leading zeros no applied. date has to be entered manually. ' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	12 Nov 2020 15:15:18
User entered '02 Sep 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	12 Nov 2020 15:14:23
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:30:18
User entered '2 Sep 2020'	Chana Hines (b) (4) (b) (4)	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '14:31'	Chana Hines (b) (4)	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '02 Sep 2020 14:31'	System	12 Nov 2020 15:14:23
User entered '2 Sep 2020 14:31'	System	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Left Arm (LEFT ARM)'	Chana Hines (b) (4)	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'ONCE'	System	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 20:02:47

US3922074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 17:18:57

US3922074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '2 Sep 2020'	Michele Reynolds (b) (4)	03 Sep 2020 17:18:57

US3922074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '13:00'	Michele Reynolds (b) (4)	03 Sep 2020 17:18:57

US3922074

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '2 Sep 2020 13:00'	System	03 Sep 2020 17:18:57

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:39:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '2 Sep 2020'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '13:37'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '2 Sep 2020 13:37'	System	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '13:37'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '2 Sep 2020 13:37'	System	03 Sep 2020 17:19:27

US3922074

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Michele Reynolds (b) (4)	03 Sep 2020 17:19:34

US3922074

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '1'	System	03 Sep 2020 17:19:34

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:07:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7c704090-cfe3-4111-a867-3c5d5b0fae59'	System	02 Sep 2020 20:07:57
User entered 'Yes (Y)'	System	02 Sep 2020 20:07:57

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:07:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7c704090-cfe3-4111-a867-3c5d5b0fae59'	System	02 Sep 2020 20:07:57
User entered '97.5'	System	02 Sep 2020 20:07:57

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:07:42', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7c704090-cfe3-4111-a867-3c5d5b0fae59'	System	02 Sep 2020 20:07:57
User entered 'No (N)'	System	02 Sep 2020 20:07:57

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:07:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7c704090-cfe3-4111-a867-3c5d5b0fae59'	System	02 Sep 2020 20:07:57
User entered '02 Sep 2020 15:07'	System	02 Sep 2020 20:07:57

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 14:51'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:33:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '336aee6e-33f2-4cc4-9db8-2cdc1e1f52bf'	System	02 Sep 2020 23:33:47
User entered 'Yes (Y)'	System	02 Sep 2020 23:33:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:33:32', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '336aee6e-33f2-4cc4-9db8-2cdc1e1f52bf'	System	02 Sep 2020 23:33:47
User entered '97.8'	System	02 Sep 2020 23:33:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:33:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '336aee6e-33f2-4cc4-9db8-2cdc1e1f52bf'	System	02 Sep 2020 23:33:47
User entered 'No (N)'	System	02 Sep 2020 23:33:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:33:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '336aee6e-33f2-4cc4-9db8-2cdc1e1f52bf'	System	02 Sep 2020 23:33:47
User entered '02 Sep 2020 18:33'	System	02 Sep 2020 23:33:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 18:16'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 2'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:31:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7392474c-884f-4a8e-a00c-eab8086b8f4c'	System	03 Sep 2020 23:31:49
User entered 'Yes (Y)'	System	03 Sep 2020 23:31:49

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:31:32', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7392474c-884f-4a8e-a00c-eab8086b8f4c'	System	03 Sep 2020 23:31:49
User entered '98.7'	System	03 Sep 2020 23:31:49

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:31:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7392474c-884f-4a8e-a00c-eab8086b8f4c'	System	03 Sep 2020 23:31:49
User entered 'No (N)'	System	03 Sep 2020 23:31:49

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:31:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '7392474c-884f-4a8e-a00c-eab8086b8f4c'	System	03 Sep 2020 23:31:49
User entered '03 Sep 2020 18:31'	System	03 Sep 2020 23:31:49

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 3'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '25fac025-5977-4342-8c1c-bddb4c15a45c'	System	04 Sep 2020 23:32:39
User entered 'Yes (Y)'	System	04 Sep 2020 23:32:39

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:28', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '25fac025-5977-4342-8c1c-bddb4c15a45c'	System	04 Sep 2020 23:32:39
User entered '97.9'	System	04 Sep 2020 23:32:39

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '25fac025-5977-4342-8c1c-bddb4c15a45c'	System	04 Sep 2020 23:32:39
User entered 'No (N)'	System	04 Sep 2020 23:32:39

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:37', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '25fac025-5977-4342-8c1c-bddb4c15a45c'	System	04 Sep 2020 23:32:39
User entered '04 Sep 2020 18:32'	System	04 Sep 2020 23:32:39

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 4'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3f50a650-48a8-46a4-a346-aa458e050f95'	System	06 Sep 2020 00:07:19
User entered 'Yes (Y)'	System	06 Sep 2020 00:07:19

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:06', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3f50a650-48a8-46a4-a346-aa458e050f95'	System	06 Sep 2020 00:07:19
User entered '98.1'	System	06 Sep 2020 00:07:19

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3f50a650-48a8-46a4-a346-aa458e050f95'	System	06 Sep 2020 00:07:19
User entered 'No (N)'	System	06 Sep 2020 00:07:19

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:14', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3f50a650-48a8-46a4-a346-aa458e050f95'	System	06 Sep 2020 00:07:19
User entered '05 Sep 2020 19:07'	System	06 Sep 2020 00:07:19

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 5'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:56:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f393b206-e333-4d3c-a577-580237846074'	System	06 Sep 2020 23:56:53
User entered 'Yes (Y)'	System	06 Sep 2020 23:56:53

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:56:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f393b206-e333-4d3c-a577-580237846074' User entered '98.1'	System	06 Sep 2020 23:56:53
	System	06 Sep 2020 23:56:53

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:56:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f393b206-e333-4d3c-a577-580237846074'	System	06 Sep 2020 23:56:53
User entered 'No (N)'	System	06 Sep 2020 23:56:53

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:56:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f393b206-e333-4d3c-a577-580237846074'	System	06 Sep 2020 23:56:53
User entered '06 Sep 2020 18:56'	System	06 Sep 2020 23:56:53

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 6'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:30:57', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '07f24580-eb0b-44f1-8d24-8a32eb21f1ee'	System	07 Sep 2020 23:31:16
User entered 'Yes (Y)'	System	07 Sep 2020 23:31:16

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '07f24580-eb0b-44f1-8d24-8a32eb21f1ee'	System	07 Sep 2020 23:31:16
User entered '97.5'	System	07 Sep 2020 23:31:16

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:10', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '07f24580-eb0b-44f1-8d24-8a32eb21f1ee'	System	07 Sep 2020 23:31:16
User entered 'No (N)'	System	07 Sep 2020 23:31:16

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '07f24580-eb0b-44f1-8d24-8a32eb21f1ee'	System	07 Sep 2020 23:31:16
User entered '07 Sep 2020 18:31'	System	07 Sep 2020 23:31:16

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 7'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:35:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2cbe7e2d-85f4-469f-8671-dd19b52ce030'	System	08 Sep 2020 22:35:55
User entered 'Yes (Y)'	System	08 Sep 2020 22:35:55

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:35:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2cbe7e2d-85f4-469f-8671-dd19b52ce030'	System	08 Sep 2020 22:35:55
User entered '98.5'	System	08 Sep 2020 22:35:55

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:35:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2cbe7e2d-85f4-469f-8671-dd19b52ce030'	System	08 Sep 2020 22:35:55
User entered 'No (N)'	System	08 Sep 2020 22:35:55

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:35:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2cbe7e2d-85f4-469f-8671-dd19b52ce030'	System	08 Sep 2020 22:35:55
User entered '08 Sep 2020 17:35'	System	08 Sep 2020 22:35:55

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:11:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'eab43f13-5b0a-4b58-8e16-72561d0b78fe'	System	02 Sep 2020 20:14:06
User entered 'None (1)'	System	02 Sep 2020 20:14:06

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:11:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'eab43f13-5b0a-4b58-8e16-72561d0b78fe'	System	02 Sep 2020 20:14:06
User entered 'No (N)'	System	02 Sep 2020 20:14:06

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:12:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'eab43f13-5b0a-4b58-8e16-72561d0b78fe'	System	02 Sep 2020 20:14:06
User entered 'Yes (Y)'	System	02 Sep 2020 20:14:06

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:13:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'eab43f13-5b0a-4b58-8e16-72561d0b78fe'	System	02 Sep 2020 20:14:06
User entered '5'	System	02 Sep 2020 20:14:06

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:13:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'eab43f13-5b0a-4b58-8e16-72561d0b78fe'	System	02 Sep 2020 20:14:06
User entered 'None (1)'	System	02 Sep 2020 20:14:06

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:14:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'eab43f13-5b0a-4b58-8e16-72561d0b78fe'	System	02 Sep 2020 20:14:06
User entered '02 Sep 2020 15:14'	System	02 Sep 2020 20:14:06

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 14:51'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:33:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '51dae8da-5f33-42a8-b191-001b7124a800'	System	02 Sep 2020 23:34:22
User entered 'None (1)'	System	02 Sep 2020 23:34:22

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:33:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '51dae8da-5f33-42a8-b191-001b7124a800'	System	02 Sep 2020 23:34:22
User entered 'No (N)'	System	02 Sep 2020 23:34:22

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:33:55', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '51dae8da-5f33-42a8-b191-001b7124a800'	System	02 Sep 2020 23:34:22
User entered 'No (N)'	System	02 Sep 2020 23:34:22

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:14', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '51dae8da-5f33-42a8-b191-001b7124a800'	System	02 Sep 2020 23:34:22
User entered 'None (1)'	System	02 Sep 2020 23:34:22

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:19', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '51dae8da-5f33-42a8-b191-001b7124a800'	System	02 Sep 2020 23:34:22
User entered '02 Sep 2020 18:34'	System	02 Sep 2020 23:34:22

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 18:16'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 2'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:31:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd33e3e67-e323-4d1b-b025-e1e6a545fcdf'	System	03 Sep 2020 23:32:26
User entered 'None (1)'	System	03 Sep 2020 23:32:26

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:31:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd33e3e67-e323-4d1b-b025-e1e6a545fcdf'	System	03 Sep 2020 23:32:26
User entered 'No (N)'	System	03 Sep 2020 23:32:26

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd33e3e67-e323-4d1b-b025-e1e6a545fcdf'	System	03 Sep 2020 23:32:26
User entered 'No (N)'	System	03 Sep 2020 23:32:26

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd33e3e67-e323-4d1b-b025-e1e6a545fcdf'	System	03 Sep 2020 23:32:26
User entered 'None (1)'	System	03 Sep 2020 23:32:26

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd33e3e67-e323-4d1b-b025-e1e6a545fcdf'	System	03 Sep 2020 23:32:26
User entered '03 Sep 2020 18:32'	System	03 Sep 2020 23:32:26

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 3'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '60d73d57-231a-4aea-b77f-3a70e0f8edad'	System	04 Sep 2020 23:32:56
User entered 'None (1)'	System	04 Sep 2020 23:32:56

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '60d73d57-231a-4aea-b77f-3a70e0f8edad'	System	04 Sep 2020 23:32:56
User entered 'No (N)'	System	04 Sep 2020 23:32:56

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '60d73d57-231a-4aea-b77f-3a70e0f8edad'	System	04 Sep 2020 23:32:56
User entered 'No (N)'	System	04 Sep 2020 23:32:56

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '60d73d57-231a-4aea-b77f-3a70e0f8edad'	System	04 Sep 2020 23:32:56
User entered 'None (1)'	System	04 Sep 2020 23:32:56

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '60d73d57-231a-4aea-b77f-3a70e0f8edad'	System	04 Sep 2020 23:32:56
User entered '04 Sep 2020 18:32'	System	04 Sep 2020 23:32:56

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 4'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:17', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '73c040db-c173-4c44-b7c8-d5f04b47b50e'	System	06 Sep 2020 00:07:36
User entered 'None (1)'	System	06 Sep 2020 00:07:36

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '73c040db-c173-4c44-b7c8-d5f04b47b50e'	System	06 Sep 2020 00:07:36
User entered 'No (N)'	System	06 Sep 2020 00:07:36

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:24', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '73c040db-c173-4c44-b7c8-d5f04b47b50e'	System	06 Sep 2020 00:07:36
User entered 'No (N)'	System	06 Sep 2020 00:07:36

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '73c040db-c173-4c44-b7c8-d5f04b47b50e'	System	06 Sep 2020 00:07:36
User entered 'None (1)'	System	06 Sep 2020 00:07:36

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:31', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '73c040db-c173-4c44-b7c8-d5f04b47b50e'	System	06 Sep 2020 00:07:36
User entered '05 Sep 2020 19:07'	System	06 Sep 2020 00:07:36

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 5'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:56:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5ee0f5e2-a750-4915-aca5-8cd57f3ed059'	System	06 Sep 2020 23:57:10
User entered 'None (1)'	System	06 Sep 2020 23:57:10

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:56:57', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5ee0f5e2-a750-4915-aca5-8cd57f3ed059'	System	06 Sep 2020 23:57:10
User entered 'No (N)'	System	06 Sep 2020 23:57:10

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5ee0f5e2-a750-4915-aca5-8cd57f3ed059'	System	06 Sep 2020 23:57:10
User entered 'No (N)'	System	06 Sep 2020 23:57:10

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:04', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5ee0f5e2-a750-4915-aca5-8cd57f3ed059'	System	06 Sep 2020 23:57:10
User entered 'None (1)'	System	06 Sep 2020 23:57:10

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5ee0f5e2-a750-4915-aca5-8cd57f3ed059'	System	06 Sep 2020 23:57:10
User entered '06 Sep 2020 18:57'	System	06 Sep 2020 23:57:10

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 6'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:16', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9307e8b1-1257-4736-b2ca-7e0d9edb7efc'	System	07 Sep 2020 23:31:32
User entered 'None (1)'	System	07 Sep 2020 23:31:32

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:20', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9307e8b1-1257-4736-b2ca-7e0d9edb7efc'	System	07 Sep 2020 23:31:32
User entered 'No (N)'	System	07 Sep 2020 23:31:32

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9307e8b1-1257-4736-b2ca-7e0d9edb7efc'	System	07 Sep 2020 23:31:32
User entered 'No (N)'	System	07 Sep 2020 23:31:32

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9307e8b1-1257-4736-b2ca-7e0d9edb7efc'	System	07 Sep 2020 23:31:32
User entered 'None (1)'	System	07 Sep 2020 23:31:32

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:29', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9307e8b1-1257-4736-b2ca-7e0d9edb7efc'	System	07 Sep 2020 23:31:32
User entered '07 Sep 2020 18:31'	System	07 Sep 2020 23:31:32

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 7'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:35:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '639d9a38-40a4-4031-878b-3401c65803e9'	System	08 Sep 2020 22:36:07
User entered 'None (1)'	System	08 Sep 2020 22:36:07

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:35:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '639d9a38-40a4-4031-878b-3401c65803e9'	System	08 Sep 2020 22:36:07
User entered 'No (N)'	System	08 Sep 2020 22:36:07

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:35:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '639d9a38-40a4-4031-878b-3401c65803e9'	System	08 Sep 2020 22:36:07
User entered 'No (N)'	System	08 Sep 2020 22:36:07

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '639d9a38-40a4-4031-878b-3401c65803e9'	System	08 Sep 2020 22:36:07
User entered 'None (1)'	System	08 Sep 2020 22:36:07

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:04', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '639d9a38-40a4-4031-878b-3401c65803e9'	System	08 Sep 2020 22:36:07
User entered '08 Sep 2020 17:36'	System	08 Sep 2020 22:36:07

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:14:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered 'None (0)'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:14:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered 'None (0)'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:14:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered 'None (0)'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:14:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered 'None (0)'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:14:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered 'None (0)'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:14:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered 'None (0)'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:15:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered 'No (N)'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T15:15:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'df58dc4c-d76a-43fd-97de-5b86bcb9e271'	System	02 Sep 2020 20:15:15
User entered '02 Sep 2020 15:15'	System	02 Sep 2020 20:15:15

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 14:51'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 17:21'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered 'None (0)'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered 'None (0)'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered 'None (0)'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered 'None (0)'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered 'None (0)'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:48', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered 'None (0)'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered 'No (N)'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-02T18:34:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cbfce288-3a47-4642-8cac-84f7b5f8d906'	System	02 Sep 2020 23:35:04
User entered '02 Sep 2020 18:34'	System	02 Sep 2020 23:35:04

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Sep 2020 18:16'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 2'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered 'None (0)'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered 'No interference with activity (1)'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered 'None (0)'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered 'None (0)'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered 'None (0)'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered 'None (0)'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered 'No (N)'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-03T18:32:55', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1986d2c0-6e4c-4a9a-900b-2e85499bd4a0'	System	03 Sep 2020 23:33:00
User entered '03 Sep 2020 18:32'	System	03 Sep 2020 23:33:00

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 3'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:32:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered 'None (0)'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:33:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered 'None (0)'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:33:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered 'None (0)'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:33:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered 'None (0)'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:33:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered 'None (0)'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:33:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered 'None (0)'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:33:14', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered 'No (N)'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-04T18:33:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fb5f633d-42d6-4b77-a622-ea8a1dbb91bb'	System	04 Sep 2020 23:33:21
User entered '04 Sep 2020 18:33'	System	04 Sep 2020 23:33:21

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 4'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered 'None (0)'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:39', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered 'None (0)'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:42', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered 'None (0)'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:45', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered 'None (0)'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered 'None (0)'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered 'None (0)'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered 'No (N)'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-05T19:07:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd47aec94-086e-42da-a777-47071601a743'	System	06 Sep 2020 00:08:01
User entered '05 Sep 2020 19:07'	System	06 Sep 2020 00:08:01

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 5'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:16', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered 'None (0)'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered 'None (0)'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:20', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered 'None (0)'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered 'None (0)'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered 'None (0)'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered 'None (0)'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:31', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered 'No (N)'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-06T18:57:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c69d6243-211a-4d93-91b7-435bca83f203'	System	06 Sep 2020 23:57:38
User entered '06 Sep 2020 18:57'	System	06 Sep 2020 23:57:38

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 6'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered 'None (0)'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered 'None (0)'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered 'None (0)'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered 'None (0)'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered 'None (0)'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered 'None (0)'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:31:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered 'No (N)'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-07T18:32:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dd12fd32-22b6-48cc-a3e7-b4924d75a905'	System	07 Sep 2020 23:32:03
User entered '07 Sep 2020 18:32'	System	07 Sep 2020 23:32:03

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 7'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered 'None (0)'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered 'No interference with activity (1)'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered 'None (0)'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:24', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered 'None (0)'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered 'None (0)'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:28', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered 'None (0)'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered 'No (N)'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-08T17:36:37', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e3b41ad5-696b-454d-8c05-2c9b02af3fb9'	System	08 Sep 2020 22:36:41
User entered '08 Sep 2020 17:36'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	08 Sep 2020 22:36:41
User entered 'Day 8'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:39:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-09T18:05:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b470cf1c-7c16-46e7-9312-8c904eec48a7'	System	09 Sep 2020 23:05:55
User entered 'No interference with activity (1)'	System	09 Sep 2020 23:05:55

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-09T18:05:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b470cf1c-7c16-46e7-9312-8c904eec48a7'	System	09 Sep 2020 23:05:55
User entered '09 Sep 2020 18:05'	System	09 Sep 2020 23:05:55

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	08 Sep 2020 22:36:41
User entered 'Day 9'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:39:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-10T18:31:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '45bcfb7b-5d67-49b3-97b3-1eda193ec4e3'	System	10 Sep 2020 23:31:14
User entered 'None (0)'	System	10 Sep 2020 23:31:14

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-10T18:31:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '45bcfb7b-5d67-49b3-97b3-1eda193ec4e3'	System	10 Sep 2020 23:31:14
User entered '10 Sep 2020 18:31'	System	10 Sep 2020 23:31:14

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	08 Sep 2020 22:36:41
User entered 'Day 8'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-09T18:05:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2205efed-cb1f-482c-9c39-b41bd8e34833'	System	09 Sep 2020 23:06:03
User entered 'No (N)'	System	09 Sep 2020 23:06:03

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-09T18:05:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2205efed-cb1f-482c-9c39-b41bd8e34833'	System	09 Sep 2020 23:06:03
User entered '09 Sep 2020 18:05'	System	09 Sep 2020 23:06:03

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	08 Sep 2020 22:36:41
User entered 'Day 9'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-10T18:31:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a8203943-d82f-48c5-82d7-53a114c222dc'	System	10 Sep 2020 23:31:25
User entered 'No (N)'	System	10 Sep 2020 23:31:25

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-09-10T18:31:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a8203943-d82f-48c5-82d7-53a114c222dc'	System	10 Sep 2020 23:31:25
User entered '10 Sep 2020 18:31'	System	10 Sep 2020 23:31:25

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:36:41

US3922074

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:36:41

US3922074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Jacklyn Newton (b) (4)	09 Sep 2020 22:41:45

US3922074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '9 Sep 2020'	Jacklyn Newton (b) (4)	09 Sep 2020 22:41:45

US3922074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Contact Made (CONTACT MADE)'	Jacklyn Newton (b) (4)	09 Sep 2020 22:41:45

US3922074

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Jacklyn Newton (b) (4)	09 Sep 2020 22:41:45

US3922074

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Jacklyn Newton (b) (4)	09 Sep 2020 22:41:48

US3922074

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'I'	System	09 Sep 2020 22:41:48

US3922074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Lorine Cook (b) (4)	16 Sep 2020 22:16:53

US3922074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '16 Sep 2020'	Lorine Cook (b) (4)	16 Sep 2020 22:16:53

US3922074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Contact Made (CONTACT MADE)'	Lorine Cook (b) (4)	16 Sep 2020 22:16:53

US3922074

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	Lorine Cook (b) (4)	16 Sep 2020 22:16:53

US3922074

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Lorine Cook (b) (4)	16 Sep 2020 22:17:01

US3922074

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '1'	System	16 Sep 2020 22:17:01

US3922074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pamela Echols (b) (4)	23 Sep 2020 18:04:59

US3922074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '23 Sep 2020'	Pamela Echols (b) (4)	23 Sep 2020 18:04:59

US3922074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Contact Made (CONTACT MADE)'	Pamela Echols (b) (4)	23 Sep 2020 18:04:59

US3922074

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	Pamela Echols (b) (4)	23 Sep 2020 18:04:59

US3922074

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pamela Echols (b) (4)	23 Sep 2020 18:05:11

US3922074

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '1'	System	23 Sep 2020 18:05:11

US3922074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Chana Hines (b) (4)	02 Oct 2020 17:58:08

US3922074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:50:00
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	16 Nov 2020 15:54:30
User entered '02 Oct 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	16 Nov 2020 15:54:25
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:30:41
User entered '2 Oct 2020'	Chana Hines (b) (4) (b) (4)	02 Oct 2020 17:58:08

US3922074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Clinic (Clinic)'	Chana Hines (b) (4)	02 Oct 2020 17:58:08

US3922074

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'VISIT2'	System	02 Oct 2020 17:58:08

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User accepted default value 'Pre-Dose (PREDOSE)'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29
	(b) (4)	

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '02 Oct 2020'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '11:12'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered '02 Oct 2020 11:12'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '97.9' F	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Oral (Oral)'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '68'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'bpm'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '16'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'breaths/min'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '132'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'mmHg'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '81'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'mmHg'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User accepted default value 'Post-Dose (POSTDOSE)'	Pauline Jackson (b) (4) (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '02 Oct 2020'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '13:18'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered '02 Oct 2020 13:18'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '97.8' F	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Oral (Oral)'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '61'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'bpm'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:12:38
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'per source RR NCS' (Site from DM).	Pauline Jackson (b) (4)	26 Oct 2020 16:36:44
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:51:40
User entered '26'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'breaths/min'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '131'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'mmHg'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '81'	Pauline Jackson (b) (4)	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'mmHg'	System	16 Oct 2020 20:55:29

US3922074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:08

US3922074

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '2 Oct 2020'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:08

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Chana Hines (b) (4)	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Chana Hines (b) (4)	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

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)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Chana Hines (b) (4)	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:53:04
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	13 Nov 2020 14:11:07
User entered '02 Oct 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	13 Nov 2020 14:11:02
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:30:59
User entered '2 Oct 2020'	Chana Hines (b) (4) (b) (4)	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '12:47'	Chana Hines (b) (4)	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered '02 Oct 2020 12:47'	System	13 Nov 2020 14:11:02
User entered '2 Oct 2020 12:47'	System	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Left Arm (LEFT ARM)'	Chana Hines (b) (4)	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'ONCE'	System	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:39:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 17:58:56

US3922074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:28

US3922074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 07:39:29
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:33:35
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' canceled (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:31:58
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:31:11
User entered '2 Oct 2020'	Pauline Jackson (b) (4) (b) (4)	16 Oct 2020 20:56:28

US3922074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '11:37'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:28

US3922074

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered '2 Oct 2020 11:37'	System	16 Oct 2020 20:56:28

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:39:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 06:53:27
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	16 Nov 2020 15:55:09
User entered '02 Oct 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	16 Nov 2020 15:54:49
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 02-OCT-2020). Leading zeroes are acceptable, if applicable. Please update accordingly. Thank you' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 07:31:31
User entered '2 Oct 2020'	Pauline Jackson (b) (4) (b) (4)	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Pauline Jackson (b) (4) (b) (4)	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '11:52'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '02 Oct 2020 11:52'	System	16 Nov 2020 15:54:49
User entered '2 Oct 2020 11:52'	System	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Pauline Jackson (b) (4) (b) (4)	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Pauline Jackson (b) (4)	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered empty.	System	16 Oct 2020 20:56:40

US3922074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	16 Oct 2020 20:56:45

US3922074

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered '1'	System	16 Oct 2020 20:56:45

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:20:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1909dd3a-42c2-465f-9fa8-3324544fff54'	System	02 Oct 2020 18:20:48
User entered 'Yes (Y)'	System	02 Oct 2020 18:20:48

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:20:31', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1909dd3a-42c2-465f-9fa8-3324544fff54'	System	02 Oct 2020 18:20:48
User entered '97.8'	System	02 Oct 2020 18:20:48

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:20:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1909dd3a-42c2-465f-9fa8-3324544fff54'	System	02 Oct 2020 18:20:48
User entered 'No (N)'	System	02 Oct 2020 18:20:48

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:20:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1909dd3a-42c2-465f-9fa8-3324544fff54'	System	02 Oct 2020 18:20:48
User entered '02 Oct 2020 13:20'	System	02 Oct 2020 18:20:48

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 13:07'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 15:37'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '47949822-f945-444f-ba25-16566da2e675'	System	02 Oct 2020 23:32:22
User entered 'Yes (Y)'	System	02 Oct 2020 23:32:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '47949822-f945-444f-ba25-16566da2e675'	System	02 Oct 2020 23:32:22
User entered '98.1'	System	02 Oct 2020 23:32:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '47949822-f945-444f-ba25-16566da2e675'	System	02 Oct 2020 23:32:22
User entered 'No (N)'	System	02 Oct 2020 23:32:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:19', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '47949822-f945-444f-ba25-16566da2e675'	System	02 Oct 2020 23:32:22
User entered '02 Oct 2020 18:32'	System	02 Oct 2020 23:32:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 16:32'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 2'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:06:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '333a44d7-f10f-4892-93d6-1a9892202015'	System	03 Oct 2020 23:07:17
User entered 'Yes (Y)'	System	03 Oct 2020 23:07:17

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:06:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '333a44d7-f10f-4892-93d6-1a9892202015' User entered '98.7'	System	03 Oct 2020 23:07:17

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:07:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '333a44d7-f10f-4892-93d6-1a9892202015'	System	03 Oct 2020 23:07:17
User entered 'Yes (Y)'	System	03 Oct 2020 23:07:17

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:35:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:07:10', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '333a44d7-f10f-4892-93d6-1a9892202015'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:05:04
User entered '1'	System	03 Oct 2020 23:07:17

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:07:10', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '333a44d7-f10f-4892-93d6-1a9892202015' User entered '0'	System	03 Oct 2020 23:07:17
	System	03 Oct 2020 23:07:17

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:07:14', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '333a44d7-f10f-4892-93d6-1a9892202015' User entered '03 Oct 2020 18:07'	System	03 Oct 2020 23:07:17
	System	03 Oct 2020 23:07:17

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 3'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b9942062-11ab-4305-9518-a5acf8dd7b27'	System	04 Oct 2020 23:32:32
User entered 'Yes (Y)'	System	04 Oct 2020 23:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b9942062-11ab-4305-9518-a5acf8dd7b27'	System	04 Oct 2020 23:32:32
User entered '99.1'	System	04 Oct 2020 23:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:19', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b9942062-11ab-4305-9518-a5acf8dd7b27'	System	04 Oct 2020 23:32:32
User entered 'Yes (Y)'	System	04 Oct 2020 23:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:35:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b9942062-11ab-4305-9518-a5acf8dd7b27'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:05:09
User entered '1'	System	04 Oct 2020 23:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b9942062-11ab-4305-9518-a5acf8dd7b27'	System	04 Oct 2020 23:32:32
User entered '0'	System	04 Oct 2020 23:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:29', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b9942062-11ab-4305-9518-a5acf8dd7b27'	System	04 Oct 2020 23:32:32
User entered '04 Oct 2020 18:32'	System	04 Oct 2020 23:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 4'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:39:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '79869c2d-a8f1-43c3-b998-b4482bf129d7'	System	05 Oct 2020 22:39:55
User entered 'Yes (Y)'	System	05 Oct 2020 22:39:55

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:39:39', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '79869c2d-a8f1-43c3-b998-b4482bf129d7'	System	05 Oct 2020 22:39:55
User entered '98.1'	System	05 Oct 2020 22:39:55

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:39:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '79869c2d-a8f1-43c3-b998-b4482bf129d7'	System	05 Oct 2020 22:39:55
User entered 'Yes (Y)'	System	05 Oct 2020 22:39:55

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:35:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:39:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '79869c2d-a8f1-43c3-b998-b4482bf129d7'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:05:17
User entered '1'	System	05 Oct 2020 22:39:55

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:39:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '79869c2d-a8f1-43c3-b998-b4482bf129d7'	System	05 Oct 2020 22:39:55
User entered '0'	System	05 Oct 2020 22:39:55

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:39:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '79869c2d-a8f1-43c3-b998-b4482bf129d7'	System	05 Oct 2020 22:39:55
User entered '05 Oct 2020 17:39'	System	05 Oct 2020 22:39:55

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 5'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:48', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ad3c8eb1-3e18-4e80-b215-b591e5e99332'	System	06 Oct 2020 22:39:10
User entered 'Yes (Y)'	System	06 Oct 2020 22:39:10

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ad3c8eb1-3e18-4e80-b215-b591e5e99332'	System	06 Oct 2020 22:39:10
User entered '97.9'	System	06 Oct 2020 22:39:10

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:39:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ad3c8eb1-3e18-4e80-b215-b591e5e99332'	System	06 Oct 2020 22:39:10
User entered 'Yes (Y)'	System	06 Oct 2020 22:39:10

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:35:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:39:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ad3c8eb1-3e18-4e80-b215-b591e5e99332'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:05:25
User entered '1'	System	06 Oct 2020 22:39:10

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:39:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ad3c8eb1-3e18-4e80-b215-b591e5e99332'	System	06 Oct 2020 22:39:10
User entered '0'	System	06 Oct 2020 22:39:10

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:39:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ad3c8eb1-3e18-4e80-b215-b591e5e99332'	System	06 Oct 2020 22:39:10
User entered '06 Oct 2020 17:39'	System	06 Oct 2020 22:39:10

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 6'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:46:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '28eeb33a-22fd-4658-93ce-1c8d240dc475'	System	07 Oct 2020 22:47:06
User entered 'Yes (Y)'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:46:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '28eeb33a-22fd-4658-93ce-1c8d240dc475'	System	07 Oct 2020 22:47:06
User entered '97.9'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:46:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '28eeb33a-22fd-4658-93ce-1c8d240dc475'	System	07 Oct 2020 22:47:06
User entered 'Yes (Y)'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:36:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:46:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '28eeb33a-22fd-4658-93ce-1c8d240dc475'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:05:34
User entered '1'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:46:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '28eeb33a-22fd-4658-93ce-1c8d240dc475'	System	07 Oct 2020 22:47:06
User entered '0'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '28eeb33a-22fd-4658-93ce-1c8d240dc475'	System	07 Oct 2020 22:47:06
User entered '07 Oct 2020 17:47'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 7'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:01:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8479e7e2-08ad-4654-a00f-70ce54cf5a66'	System	08 Oct 2020 22:02:18
User entered 'Yes (Y)'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:01:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8479e7e2-08ad-4654-a00f-70ce54cf5a66'	System	08 Oct 2020 22:02:18
User entered '98.3'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:04', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8479e7e2-08ad-4654-a00f-70ce54cf5a66'	System	08 Oct 2020 22:02:18
User entered 'Yes (Y)'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:36:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8479e7e2-08ad-4654-a00f-70ce54cf5a66'	Pauline Jackson (b) (4)	27 Oct 2020 15:05:40
User entered '1'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8479e7e2-08ad-4654-a00f-70ce54cf5a66'	System	08 Oct 2020 22:02:18
User entered '0'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8479e7e2-08ad-4654-a00f-70ce54cf5a66'	System	08 Oct 2020 22:02:18
User entered '08 Oct 2020 17:02'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	07 Oct 2020 22:47:06
User entered 'Day 8'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:31:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6bf986e1-3ba1-4894-9bd4-5e2773e4def8'	System	09 Oct 2020 22:32:15
User entered 'Yes (Y)'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:31:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6bf986e1-3ba1-4894-9bd4-5e2773e4def8'	System	09 Oct 2020 22:32:15
User entered '97.5'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:31:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6bf986e1-3ba1-4894-9bd4-5e2773e4def8'	System	09 Oct 2020 22:32:15
User entered 'Yes (Y)'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:36:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:32:06', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6bf986e1-3ba1-4894-9bd4-5e2773e4def8'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:13:29
User entered '1'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:32:06', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6bf986e1-3ba1-4894-9bd4-5e2773e4def8'	System	09 Oct 2020 22:32:15
User entered '0'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:32:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6bf986e1-3ba1-4894-9bd4-5e2773e4def8'	System	09 Oct 2020 22:32:15
User entered '09 Oct 2020 17:32'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	08 Oct 2020 22:02:18
User entered 'Day 9'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:36:48', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'de3130bf-662c-4261-bc60-1d91614aa2e1'	System	10 Oct 2020 22:37:07
User entered 'Yes (Y)'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:36:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'de3130bf-662c-4261-bc60-1d91614aa2e1'	System	10 Oct 2020 22:37:07
User entered '97.5'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:36:57', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'de3130bf-662c-4261-bc60-1d91614aa2e1'	System	10 Oct 2020 22:37:07
User entered 'Yes (Y)'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:36:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:36:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'de3130bf-662c-4261-bc60-1d91614aa2e1'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:13:34
User entered '1'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:36:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'de3130bf-662c-4261-bc60-1d91614aa2e1' User entered '0'	System	10 Oct 2020 22:37:07
	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:37:02', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'de3130bf-662c-4261-bc60-1d91614aa2e1'	System	10 Oct 2020 22:37:07
User entered '10 Oct 2020 17:37'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	09 Oct 2020 22:32:15
User entered 'Day 10'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:24', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c7f0fab3-e100-4b12-82e4-03ccf725ede0'	System	11 Oct 2020 22:57:41
User entered 'Yes (Y)'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c7f0fab3-e100-4b12-82e4-03ccf725ede0'	System	11 Oct 2020 22:57:41
User entered '97.8'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c7f0fab3-e100-4b12-82e4-03ccf725ede0'	System	11 Oct 2020 22:57:41
User entered 'Yes (Y)'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:36:47
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c7f0fab3-e100-4b12-82e4-03ccf725ede0'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:13:57
User entered '1'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c7f0fab3-e100-4b12-82e4-03ccf725ede0'	System	11 Oct 2020 22:57:41
User entered '0'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c7f0fab3-e100-4b12-82e4-03ccf725ede0'	System	11 Oct 2020 22:57:41
User entered '11 Oct 2020 17:57'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(10)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	10 Oct 2020 22:37:07
User entered 'Day 11'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:28', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6d79e5ff-f9fc-45ab-9d7e-78604c022eff'	System	12 Oct 2020 22:34:46
User entered 'Yes (Y)'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6d79e5ff-f9fc-45ab-9d7e-78604c022eff'	System	12 Oct 2020 22:34:46
User entered '98.5'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6d79e5ff-f9fc-45ab-9d7e-78604c022eff'	System	12 Oct 2020 22:34:46
User entered 'Yes (Y)'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:36:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6d79e5ff-f9fc-45ab-9d7e-78604c022eff'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:14:02
User entered '1'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6d79e5ff-f9fc-45ab-9d7e-78604c022eff'	System	12 Oct 2020 22:34:46
User entered '0'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6d79e5ff-f9fc-45ab-9d7e-78604c022eff'	System	12 Oct 2020 22:34:46
User entered '12 Oct 2020 17:34'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(11)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	11 Oct 2020 22:57:41
User entered 'Day 12'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:04', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '13edcfd4-9df8-46a8-883b-c53da4645958'	System	13 Oct 2020 22:59:27
User entered 'Yes (Y)'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '13edcfd4-9df8-46a8-883b-c53da4645958'	System	13 Oct 2020 22:59:27
User entered '98.1'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '13edcfd4-9df8-46a8-883b-c53da4645958'	System	13 Oct 2020 22:59:27
User entered 'Yes (Y)'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '13edcfd4-9df8-46a8-883b-c53da4645958'	System	13 Oct 2020 22:59:27
User entered '0'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:37:50
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '13edcfd4-9df8-46a8-883b-c53da4645958'	Pauline Jackson (b) (4)	27 Oct 2020 15:14:08
User entered '1'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:24', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '13edcfd4-9df8-46a8-883b-c53da4645958'	System	13 Oct 2020 22:59:27
User entered '13 Oct 2020 17:59'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(12)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	12 Oct 2020 22:34:46
User entered 'Day 13'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '317afd78-a1a5-48dc-903a-5234a74e9702'	System	14 Oct 2020 21:36:30
User entered 'Yes (Y)'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:06', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '317afd78-a1a5-48dc-903a-5234a74e9702'	System	14 Oct 2020 21:36:30
User entered '97.8'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '317afd78-a1a5-48dc-903a-5234a74e9702'	System	14 Oct 2020 21:36:30
User entered 'Yes (Y)'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:38:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '317afd78-a1a5-48dc-903a-5234a74e9702'	Pauline Jackson (b) (4)	27 Oct 2020 15:14:59
User entered '1'	System	14 Oct 2020 21:36:30
	System	14 Oct 2020 21:36:30
	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '317afd78-a1a5-48dc-903a-5234a74e9702'	System	14 Oct 2020 21:36:30
User entered '0'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '317afd78-a1a5-48dc-903a-5234a74e9702'	System	14 Oct 2020 21:36:30
User entered '14 Oct 2020 17:36'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(13)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	13 Oct 2020 22:59:27
User entered 'Day 14'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9072fc47-6da6-4d66-9736-2f441b6318ac'	System	15 Oct 2020 21:31:56
User entered 'Yes (Y)'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9072fc47-6da6-4d66-9736-2f441b6318ac'	System	15 Oct 2020 21:31:56
User entered '97.3'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:45', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9072fc47-6da6-4d66-9736-2f441b6318ac'	System	15 Oct 2020 21:31:56
User entered 'Yes (Y)'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:38:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9072fc47-6da6-4d66-9736-2f441b6318ac'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:06
User entered '1'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9072fc47-6da6-4d66-9736-2f441b6318ac'	System	15 Oct 2020 21:31:56
User entered '0'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9072fc47-6da6-4d66-9736-2f441b6318ac'	System	15 Oct 2020 21:31:56
User entered '15 Oct 2020 17:31'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(14)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	14 Oct 2020 21:36:30
User entered 'Day 15'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd8ebd8f9-acc5-4a9f-aafa-ab377ed9a6bd'	System	16 Oct 2020 20:58:27
User entered 'Yes (Y)'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd8ebd8f9-acc5-4a9f-aafa-ab377ed9a6bd'	System	16 Oct 2020 20:58:27
User entered '98.1'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd8ebd8f9-acc5-4a9f-aafa-ab377ed9a6bd'	System	16 Oct 2020 20:58:27
User entered 'Yes (Y)'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:38:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:20', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd8ebd8f9-acc5-4a9f-aafa-ab377ed9a6bd'	Pauline Jackson (b) (4)	27 Oct 2020 15:15:11
User entered '1'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:20', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd8ebd8f9-acc5-4a9f-aafa-ab377ed9a6bd'	System	16 Oct 2020 20:58:27
User entered '0'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd8ebd8f9-acc5-4a9f-aafa-ab377ed9a6bd'	System	16 Oct 2020 20:58:27
User entered '16 Oct 2020 16:58'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(15)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	15 Oct 2020 21:31:56
User entered 'Day 16'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:05:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172bfc5-7d71-408e-8707-52286f6502e1'	System	17 Oct 2020 22:06:06
User entered 'Yes (Y)'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:05:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172bfc5-7d71-408e-8707-52286f6502e1' User entered '97.5'	System	17 Oct 2020 22:06:06
	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:05:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172bfc5-7d71-408e-8707-52286f6502e1'	System	17 Oct 2020 22:06:06
User entered 'Yes (Y)'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:38:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:06:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172bfc5-7d71-408e-8707-52286f6502e1'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:17
User entered '1'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:06:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172bfc5-7d71-408e-8707-52286f6502e1' User entered '0'	System	17 Oct 2020 22:06:06
	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:06:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172bfc5-7d71-408e-8707-52286f6502e1' User entered '17 Oct 2020 18:06'	System	17 Oct 2020 22:06:06
	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(16)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	16 Oct 2020 20:58:27
User entered 'Day 17'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6314b83b-e8e5-433c-a5a2-c367c2ed27d2'	System	18 Oct 2020 20:32:54
User entered 'Yes (Y)'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6314b83b-e8e5-433c-a5a2-c367c2ed27d2'	System	18 Oct 2020 20:32:54
User entered '98.1'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6314b83b-e8e5-433c-a5a2-c367c2ed27d2'	System	18 Oct 2020 20:32:54
User entered 'Yes (Y)'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:38:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6314b83b-e8e5-433c-a5a2-c367c2ed27d2'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:22
User entered '1'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6314b83b-e8e5-433c-a5a2-c367c2ed27d2'	System	18 Oct 2020 20:32:54
User entered '0'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6314b83b-e8e5-433c-a5a2-c367c2ed27d2'	System	18 Oct 2020 20:32:54
User entered '18 Oct 2020 16:32'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(17)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	17 Oct 2020 22:06:06
User entered 'Day 18'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fc722047-1292-4550-9ba3-256f3745ceaf'	System	19 Oct 2020 20:34:42
User entered 'Yes (Y)'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fc722047-1292-4550-9ba3-256f3745ceaf'	System	19 Oct 2020 20:34:42
User entered '98.1'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:35', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fc722047-1292-4550-9ba3-256f3745ceaf'	System	19 Oct 2020 20:34:42
User entered 'Yes (Y)'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:38:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:37', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fc722047-1292-4550-9ba3-256f3745ceaf'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:27
User entered '1'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:37', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fc722047-1292-4550-9ba3-256f3745ceaf'	System	19 Oct 2020 20:34:42
User entered '0'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'fc722047-1292-4550-9ba3-256f3745ceaf'	System	19 Oct 2020 20:34:42
User entered '19 Oct 2020 16:34'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(18)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	18 Oct 2020 20:32:54
User entered 'Day 19'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(19)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	19 Oct 2020 20:34:42
User entered 'Day 20'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:15:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f9831392-6531-4aec-8b0a-f0bc69e713f7'	System	21 Oct 2020 22:16:19
User entered 'Yes (Y)'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:16:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f9831392-6531-4aec-8b0a-f0bc69e713f7'	System	21 Oct 2020 22:16:19
User entered '97.5'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:16:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f9831392-6531-4aec-8b0a-f0bc69e713f7'	System	21 Oct 2020 22:16:19
User entered 'Yes (Y)'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:39:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:16:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f9831392-6531-4aec-8b0a-f0bc69e713f7'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:39
User entered '1'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:16:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f9831392-6531-4aec-8b0a-f0bc69e713f7'	System	21 Oct 2020 22:16:19
User entered '0'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:16:14', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f9831392-6531-4aec-8b0a-f0bc69e713f7'	System	21 Oct 2020 22:16:19
User entered '21 Oct 2020 18:16'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(20)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	21 Oct 2020 22:16:19
User entered 'Day 21'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc291a7b-aacd-4a61-a9d9-3729b0b91643'	System	22 Oct 2020 21:31:20
User entered 'Yes (Y)'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc291a7b-aacd-4a61-a9d9-3729b0b91643'	System	22 Oct 2020 21:31:20
User entered '97.8'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:13', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc291a7b-aacd-4a61-a9d9-3729b0b91643'	System	22 Oct 2020 21:31:20
User entered 'Yes (Y)'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:39:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc291a7b-aacd-4a61-a9d9-3729b0b91643'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:43
User entered '1'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc291a7b-aacd-4a61-a9d9-3729b0b91643'	System	22 Oct 2020 21:31:20
User entered '0'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc291a7b-aacd-4a61-a9d9-3729b0b91643'	System	22 Oct 2020 21:31:20
User entered '22 Oct 2020 17:31'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(21)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	21 Oct 2020 22:16:19
User entered 'Day 22'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b33a0086-f2b4-489d-93c9-98e5fc390f10'	System	23 Oct 2020 18:25:43
User entered 'Yes (Y)'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b33a0086-f2b4-489d-93c9-98e5fc390f10'	System	23 Oct 2020 18:25:43
User entered '98.1'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b33a0086-f2b4-489d-93c9-98e5fc390f10'	System	23 Oct 2020 18:25:43
User entered 'Yes (Y)'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:39:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b33a0086-f2b4-489d-93c9-98e5fc390f10'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:48
User entered '1'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b33a0086-f2b4-489d-93c9-98e5fc390f10'	System	23 Oct 2020 18:25:43
User entered '0'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b33a0086-f2b4-489d-93c9-98e5fc390f10'	System	23 Oct 2020 18:25:43
User entered '23 Oct 2020 14:25'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(22)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	22 Oct 2020 21:31:20
User entered 'Day 23'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:58:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5616eccb-6722-4eab-80f4-611ca43dd83b'	System	25 Oct 2020 01:59:05
User entered 'Yes (Y)'	System	25 Oct 2020 01:59:05

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:58:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5616eccb-6722-4eab-80f4-611ca43dd83b'	System	25 Oct 2020 01:59:05
User entered '97.8'	System	25 Oct 2020 01:59:05

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:58:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5616eccb-6722-4eab-80f4-611ca43dd83b'	System	25 Oct 2020 01:59:05
User entered 'Yes (Y)'	System	25 Oct 2020 01:59:05

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and documented in source. medication added to con med eCRF' (Site from System).	(b) (4), (b) (6)	29 Oct 2020 11:39:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:59:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5616eccb-6722-4eab-80f4-611ca43dd83b'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:15:53
User entered '1'	System	25 Oct 2020 01:59:05

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:59:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5616eccb-6722-4eab-80f4-611ca43dd83b'	System	25 Oct 2020 01:59:05
User entered '0'	System	25 Oct 2020 01:59:05

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:59:02', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5616eccb-6722-4eab-80f4-611ca43dd83b'	System	25 Oct 2020 01:59:05
User entered '24 Oct 2020 20:59'	System	25 Oct 2020 01:59:05

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(23)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	23 Oct 2020 18:25:43
User entered 'Day 24'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-25T21:15:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4463ad9c-1995-4fc0-a6a4-7e10d121d870'	System	26 Oct 2020 02:15:30
User entered 'Yes (Y)'	System	26 Oct 2020 02:15:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-25T21:15:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4463ad9c-1995-4fc0-a6a4-7e10d121d870'	System	26 Oct 2020 02:15:30
User entered '97.2'	System	26 Oct 2020 02:15:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-25T21:15:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4463ad9c-1995-4fc0-a6a4-7e10d121d870'	System	26 Oct 2020 02:15:30
User entered 'No (N)'	System	26 Oct 2020 02:15:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-25T21:15:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4463ad9c-1995-4fc0-a6a4-7e10d121d870'	System	26 Oct 2020 02:15:30
User entered '25 Oct 2020 21:15'	System	26 Oct 2020 02:15:30

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Temperature_Day(24)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:20:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8e131b0e-366b-4c71-87ca-38fc670a9792'	System	02 Oct 2020 18:21:23
User entered 'None (1)'	System	02 Oct 2020 18:21:23

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:20:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8e131b0e-366b-4c71-87ca-38fc670a9792'	System	02 Oct 2020 18:21:23
User entered 'No (N)'	System	02 Oct 2020 18:21:23

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8e131b0e-366b-4c71-87ca-38fc670a9792'	System	02 Oct 2020 18:21:23
User entered 'No (N)'	System	02 Oct 2020 18:21:23

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:14', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8e131b0e-366b-4c71-87ca-38fc670a9792'	System	02 Oct 2020 18:21:23
User entered 'None (1)'	System	02 Oct 2020 18:21:23

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:17', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8e131b0e-366b-4c71-87ca-38fc670a9792'	System	02 Oct 2020 18:21:23
User entered '02 Oct 2020 13:21'	System	02 Oct 2020 18:21:23

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 13:07'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 15:37'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '67f4d8f6-56d2-4da8-a7b8-8eced73a7bf2'	System	02 Oct 2020 23:32:49
User entered 'None (1)'	System	02 Oct 2020 23:32:49

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:31', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '67f4d8f6-56d2-4da8-a7b8-8eced73a7bf2'	System	02 Oct 2020 23:32:49
User entered 'No (N)'	System	02 Oct 2020 23:32:49

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '67f4d8f6-56d2-4da8-a7b8-8eced73a7bf2'	System	02 Oct 2020 23:32:49
User entered 'No (N)'	System	02 Oct 2020 23:32:49

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '67f4d8f6-56d2-4da8-a7b8-8eced73a7bf2'	System	02 Oct 2020 23:32:49
User entered 'None (1)'	System	02 Oct 2020 23:32:49

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '67f4d8f6-56d2-4da8-a7b8-8eced73a7bf2'	System	02 Oct 2020 23:32:49
User entered '02 Oct 2020 18:32'	System	02 Oct 2020 23:32:49

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 16:32'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 2'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:07:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f1d1bd60-7071-48bc-a8f0-8792c8411a83'	System	03 Oct 2020 23:08:46
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 23:08:46

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:07:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f1d1bd60-7071-48bc-a8f0-8792c8411a83'	System	03 Oct 2020 23:08:46
User entered 'No (N)'	System	03 Oct 2020 23:08:46

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:08:37', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f1d1bd60-7071-48bc-a8f0-8792c8411a83'	System	03 Oct 2020 23:08:46
User entered 'No (N)'	System	03 Oct 2020 23:08:46

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:08:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f1d1bd60-7071-48bc-a8f0-8792c8411a83'	System	03 Oct 2020 23:08:46
User entered 'None (1)'	System	03 Oct 2020 23:08:46

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:08:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f1d1bd60-7071-48bc-a8f0-8792c8411a83'	System	03 Oct 2020 23:08:46
User entered '03 Oct 2020 18:08'	System	03 Oct 2020 23:08:46

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 3'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '197cef0c-0be1-4122-8357-d32b5c8e3ab0'	System	04 Oct 2020 23:33:17
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Oct 2020 23:33:17

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:32:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '197cef0c-0be1-4122-8357-d32b5c8e3ab0'	System	04 Oct 2020 23:33:17
User entered 'No (N)'	System	04 Oct 2020 23:33:17

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:06', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '197cef0c-0be1-4122-8357-d32b5c8e3ab0'	System	04 Oct 2020 23:33:17
User entered 'No (N)'	System	04 Oct 2020 23:33:17

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '197cef0c-0be1-4122-8357-d32b5c8e3ab0'	System	04 Oct 2020 23:33:17
User entered 'None (1)'	System	04 Oct 2020 23:33:17

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '197cef0c-0be1-4122-8357-d32b5c8e3ab0'	System	04 Oct 2020 23:33:17
User entered '04 Oct 2020 18:33'	System	04 Oct 2020 23:33:17

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 4'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:40:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1ad0a684-535f-4e11-9641-12f20dafa98b'	System	05 Oct 2020 22:42:08
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 22:42:08

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:40:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1ad0a684-535f-4e11-9641-12f20dafa98b'	System	05 Oct 2020 22:42:08
User entered 'No (N)'	System	05 Oct 2020 22:42:08

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:40:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1ad0a684-535f-4e11-9641-12f20dafa98b'	System	05 Oct 2020 22:42:08
User entered 'Yes (Y)'	System	05 Oct 2020 22:42:08

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:41:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1ad0a684-535f-4e11-9641-12f20dafa98b'	System	05 Oct 2020 22:42:08
User entered '250'	System	05 Oct 2020 22:42:08

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:41:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1ad0a684-535f-4e11-9641-12f20dafa98b'	System	05 Oct 2020 22:42:08
User entered 'None (1)'	System	05 Oct 2020 22:42:08

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1ad0a684-535f-4e11-9641-12f20dafa98b'	System	05 Oct 2020 22:42:08
User entered '05 Oct 2020 17:42'	System	05 Oct 2020 22:42:08

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 5'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:37:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '032b4aca-8531-4c26-a2e6-d851ea3aa596'	System	06 Oct 2020 22:38:10
User entered 'None (1)'	System	06 Oct 2020 22:38:10

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:37:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '032b4aca-8531-4c26-a2e6-d851ea3aa596'	System	06 Oct 2020 22:38:10
User entered 'No (N)'	System	06 Oct 2020 22:38:10

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '032b4aca-8531-4c26-a2e6-d851ea3aa596'	System	06 Oct 2020 22:38:10
User entered 'No (N)'	System	06 Oct 2020 22:38:10

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '032b4aca-8531-4c26-a2e6-d851ea3aa596'	System	06 Oct 2020 22:38:10
User entered 'None (1)'	System	06 Oct 2020 22:38:10

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '032b4aca-8531-4c26-a2e6-d851ea3aa596'	System	06 Oct 2020 22:38:10
User entered '06 Oct 2020 17:38'	System	06 Oct 2020 22:38:10

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 6'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1a9bf877-f2fe-451a-87c5-cb825c77042d'	System	07 Oct 2020 22:47:25
User entered 'None (1)'	System	07 Oct 2020 22:47:25

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:13', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1a9bf877-f2fe-451a-87c5-cb825c77042d'	System	07 Oct 2020 22:47:25
User entered 'No (N)'	System	07 Oct 2020 22:47:25

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1a9bf877-f2fe-451a-87c5-cb825c77042d'	System	07 Oct 2020 22:47:25
User entered 'No (N)'	System	07 Oct 2020 22:47:25

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:19', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1a9bf877-f2fe-451a-87c5-cb825c77042d'	System	07 Oct 2020 22:47:25
User entered 'None (1)'	System	07 Oct 2020 22:47:25

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1a9bf877-f2fe-451a-87c5-cb825c77042d'	System	07 Oct 2020 22:47:25
User entered '07 Oct 2020 17:47'	System	07 Oct 2020 22:47:25

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 7'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:16', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'afd79c36-b887-4690-b324-b9a92d316240'	System	08 Oct 2020 22:02:28
User entered 'None (1)'	System	08 Oct 2020 22:02:28

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:19', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'afd79c36-b887-4690-b324-b9a92d316240'	System	08 Oct 2020 22:02:28
User entered 'No (N)'	System	08 Oct 2020 22:02:28

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'afd79c36-b887-4690-b324-b9a92d316240'	System	08 Oct 2020 22:02:28
User entered 'No (N)'	System	08 Oct 2020 22:02:28

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'afd79c36-b887-4690-b324-b9a92d316240'	System	08 Oct 2020 22:02:28
User entered 'None (1)'	System	08 Oct 2020 22:02:28

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'afd79c36-b887-4690-b324-b9a92d316240'	System	08 Oct 2020 22:02:28
User entered '08 Oct 2020 17:02'	System	08 Oct 2020 22:02:28

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered 'None (0)'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered 'None (0)'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:29', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered 'None (0)'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered 'None (0)'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered 'None (0)'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered 'None (0)'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:45', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered 'No (N)'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T13:21:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b72dc17-d589-4713-b321-9397b553e0f5'	System	02 Oct 2020 18:21:56
User entered '02 Oct 2020 13:21'	System	02 Oct 2020 18:21:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 13:07'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 15:37'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered 'None (0)'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered 'None (0)'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered 'None (0)'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:32:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered 'None (0)'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:33:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered 'None (0)'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:33:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered 'None (0)'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:33:06', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered 'No (N)'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-02T18:33:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0ebd570-edbf-4195-9418-40aa854df9ff'	System	02 Oct 2020 23:33:11
User entered '02 Oct 2020 18:33'	System	02 Oct 2020 23:33:11

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '02 Oct 2020 16:32'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 2'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:08:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered 'No interference with activity (1)'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:08:55', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered 'Some interference with activity (2)'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:08:59', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered 'Some interference with activity (2)'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:09:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered 'No interference with activity (1)'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:09:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered 'None (0)'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:09:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered 'Some interference with activity not requiring medical attention (2)'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:09:37', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered 'No (N)'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-03T18:09:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6606b788-8616-4dcb-9f92-f8130def9c35'	System	03 Oct 2020 23:09:43
User entered '03 Oct 2020 18:09'	System	03 Oct 2020 23:09:43

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 3'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:16', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered 'None (0)'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered 'Some interference with activity (2)'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered 'None (0)'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:31', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered 'No interference with activity (1)'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered 'None (0)'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered 'None (0)'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered 'No (N)'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-04T18:33:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3bf22da5-54ea-4168-96e7-881507fee6e6'	System	04 Oct 2020 23:33:51
User entered '04 Oct 2020 18:33'	System	04 Oct 2020 23:33:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 4'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered 'None (0)'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered 'None (0)'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:15', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered 'None (0)'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:19', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered 'None (0)'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered 'None (0)'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:24', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered 'None (0)'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:29', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered 'No (N)'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-05T17:42:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'bcc3e3ff-7c33-4e23-887f-4294c55f5e8b'	System	05 Oct 2020 22:42:36
User entered '05 Oct 2020 17:42'	System	05 Oct 2020 22:42:36

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 5'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:13', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered 'None (0)'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:19', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered 'Some interference with activity (2)'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:24', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered 'No interference with activity (1)'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:28', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered 'No interference with activity (1)'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered 'None (0)'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered 'None (0)'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered 'No (N)'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-06T17:38:39', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '98d80129-a01e-4756-8801-efaece1403b5'	System	06 Oct 2020 22:38:41
User entered '06 Oct 2020 17:38'	System	06 Oct 2020 22:38:41

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 6'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered 'None (0)'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered 'No interference with activity (1)'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered 'None (0)'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered 'None (0)'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered 'No (N)'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-07T17:47:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4521270c-df32-4cdb-8002-86ea799bc6c1'	System	07 Oct 2020 22:47:49
User entered '07 Oct 2020 17:47'	System	07 Oct 2020 22:47:49

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Oct 2020 17:58:56
User entered 'Day 7'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:29', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered 'None (0)'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:32', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered 'None (0)'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered 'None (0)'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:36', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered 'None (0)'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered 'None (0)'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered 'None (0)'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered 'No (N)'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-08T17:02:45', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9eae89a9-3820-4b61-b8e7-bc2cc44dd9ee'	System	08 Oct 2020 22:02:51
User entered '08 Oct 2020 17:02'	System	08 Oct 2020 22:02:51

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:58:56

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	07 Oct 2020 22:47:06
User entered 'Day 8'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:32:22', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a4b7022b-e178-4a04-b515-630879c8c511'	System	09 Oct 2020 22:32:32
User entered 'No (N)'	System	09 Oct 2020 22:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-09T17:32:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a4b7022b-e178-4a04-b515-630879c8c511'	System	09 Oct 2020 22:32:32
User entered '09 Oct 2020 17:32'	System	09 Oct 2020 22:32:32

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 22:47:06

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	08 Oct 2020 22:02:18
User entered 'Day 9'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:37:08', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b6e1a819-e348-4b81-9936-447d76aad356'	System	10 Oct 2020 22:37:13
User entered 'No (N)'	System	10 Oct 2020 22:37:13

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-10T17:37:10', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'b6e1a819-e348-4b81-9936-447d76aad356'	System	10 Oct 2020 22:37:13
User entered '10 Oct 2020 17:37'	System	10 Oct 2020 22:37:13

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 22:02:18

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	09 Oct 2020 22:32:15
User entered 'Day 10'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4ef64403-86fc-4a63-8c27-b7000e7a810f'	System	11 Oct 2020 22:57:46
User entered 'No (N)'	System	11 Oct 2020 22:57:46

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-11T17:57:43', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4ef64403-86fc-4a63-8c27-b7000e7a810f'	System	11 Oct 2020 22:57:46
User entered '11 Oct 2020 17:57'	System	11 Oct 2020 22:57:46

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 22:32:15

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	10 Oct 2020 22:37:07
User entered 'Day 11'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4314f6b7-8a99-46df-a7f2-1e2c5d8368ba'	System	12 Oct 2020 22:34:54
User entered 'Yes (Y)'	System	12 Oct 2020 22:34:54

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-12T17:34:52', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '4314f6b7-8a99-46df-a7f2-1e2c5d8368ba'	System	12 Oct 2020 22:34:54
User entered '12 Oct 2020 17:34'	System	12 Oct 2020 22:34:54

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '12 Oct 2020 12:00'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '13 Oct 2020 11:59'	System	10 Oct 2020 22:37:07

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	11 Oct 2020 22:57:41
User entered 'Day 12'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:28', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a79da06d-c558-44f9-84e0-8666767a8f0d'	System	13 Oct 2020 22:59:34
User entered 'No (N)'	System	13 Oct 2020 22:59:34

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-13T17:59:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a79da06d-c558-44f9-84e0-8666767a8f0d'	System	13 Oct 2020 22:59:34
User entered '13 Oct 2020 17:59'	System	13 Oct 2020 22:59:34

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '13 Oct 2020 12:00'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '14 Oct 2020 11:59'	System	11 Oct 2020 22:57:41

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	12 Oct 2020 22:34:46
User entered 'Day 13'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:31', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8081aeb6-8a84-4ab3-bced-aa62b6715d9b'	System	14 Oct 2020 21:36:39
User entered 'No (N)'	System	14 Oct 2020 21:36:39

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-14T17:36:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '8081aeb6-8a84-4ab3-bced-aa62b6715d9b'	System	14 Oct 2020 21:36:39
User entered '14 Oct 2020 17:36'	System	14 Oct 2020 21:36:39

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 22:34:46

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	13 Oct 2020 22:59:27
User entered 'Day 14'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f483d1d9-99e9-42bf-8218-45641996a626'	System	15 Oct 2020 21:31:59
User entered 'No (N)'	System	15 Oct 2020 21:31:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-15T17:31:57', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'f483d1d9-99e9-42bf-8218-45641996a626'	System	15 Oct 2020 21:31:59
User entered '15 Oct 2020 17:31'	System	15 Oct 2020 21:31:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 22:59:27

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	14 Oct 2020 21:36:30
User entered 'Day 15'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a1757bd5-4b31-43cc-b200-c86799a3895a'	System	16 Oct 2020 20:58:33
User entered 'No (N)'	System	16 Oct 2020 20:58:33

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-16T16:58:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a1757bd5-4b31-43cc-b200-c86799a3895a'	System	16 Oct 2020 20:58:33
User entered '16 Oct 2020 16:58'	System	16 Oct 2020 20:58:33

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '16 Oct 2020 12:00'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '17 Oct 2020 11:59'	System	14 Oct 2020 21:36:30

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	15 Oct 2020 21:31:56
User entered 'Day 16'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:06:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '25f65dea-1826-4164-b59b-fa90814a4ced'	System	17 Oct 2020 22:06:11
User entered 'No (N)'	System	17 Oct 2020 22:06:11

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-17T18:06:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '25f65dea-1826-4164-b59b-fa90814a4ced'	System	17 Oct 2020 22:06:11
User entered '17 Oct 2020 18:06'	System	17 Oct 2020 22:06:11

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 21:31:56

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	16 Oct 2020 20:58:27
User entered 'Day 17'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0c91eb5-0977-4115-b300-a812f35d1ec9'	System	18 Oct 2020 20:32:59
User entered 'No (N)'	System	18 Oct 2020 20:32:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-18T16:32:56', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a0c91eb5-0977-4115-b300-a812f35d1ec9'	System	18 Oct 2020 20:32:59
User entered '18 Oct 2020 16:32'	System	18 Oct 2020 20:32:59

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 20:58:27

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	17 Oct 2020 22:06:06
User entered 'Day 18'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:42', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '951d9faf-3d91-4ff4-ac42-035f0e0f7f5b'	System	19 Oct 2020 20:34:47
User entered 'No (N)'	System	19 Oct 2020 20:34:47

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-19T16:34:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '951d9faf-3d91-4ff4-ac42-035f0e0f7f5b'	System	19 Oct 2020 20:34:47
User entered '19 Oct 2020 16:34'	System	19 Oct 2020 20:34:47

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '19 Oct 2020 12:00'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '20 Oct 2020 11:59'	System	17 Oct 2020 22:06:06

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	18 Oct 2020 20:32:54
User entered 'Day 19'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	25 Feb 2021 11:15:22

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '20 Oct 2020 12:00'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(19)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '21 Oct 2020 11:59'	System	18 Oct 2020 20:32:54

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	19 Oct 2020 20:34:42
User entered 'Day 20'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:16:20', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2fcd25f4-7c6a-47bd-9b9b-872d2189d4e9'	System	21 Oct 2020 22:16:26
User entered 'No (N)'	System	21 Oct 2020 22:16:26

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-21T18:16:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '2fcd25f4-7c6a-47bd-9b9b-872d2189d4e9'	System	21 Oct 2020 22:16:26
User entered '21 Oct 2020 18:16'	System	21 Oct 2020 22:16:26

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(20)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 20:34:42

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	21 Oct 2020 22:16:19
User entered 'Day 21'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5ac93a69-bf1c-4801-96c1-728c2e2c951b'	System	22 Oct 2020 21:31:45
User entered 'No (N)'	System	22 Oct 2020 21:31:45

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-22T17:31:42', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5ac93a69-bf1c-4801-96c1-728c2e2c951b'	System	22 Oct 2020 21:31:45
User entered '22 Oct 2020 17:31'	System	22 Oct 2020 21:31:45

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(21)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	21 Oct 2020 22:16:19
User entered 'Day 22'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ed508b9c-aa2c-4fed-ab14-a97db5da2ceb'	System	23 Oct 2020 18:25:45
User entered 'No (N)'	System	23 Oct 2020 18:25:45

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-23T14:25:42', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ed508b9c-aa2c-4fed-ab14-a97db5da2ceb'	System	23 Oct 2020 18:25:45
User entered '23 Oct 2020 14:25'	System	23 Oct 2020 18:25:45

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(22)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 22:16:19

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	22 Oct 2020 21:31:20
User entered 'Day 23'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:59:05', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1eac479f-bec2-4a7c-a235-13745de6e5c4'	System	25 Oct 2020 01:59:09
User entered 'No (N)'	System	25 Oct 2020 01:59:09

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-24T20:59:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '1eac479f-bec2-4a7c-a235-13745de6e5c4'	System	25 Oct 2020 01:59:09
User entered '24 Oct 2020 20:59'	System	25 Oct 2020 01:59:09

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(23)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 21:31:20

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	23 Oct 2020 18:25:43
User entered 'Day 24'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:39:26

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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-25T21:15:32', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '41668d45-abcf-452d-a73f-948d25c788e7'	System	26 Oct 2020 02:15:36
User entered 'No (N)'	System	26 Oct 2020 02:15:36

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:39:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-10-25T21:15:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '41668d45-abcf-452d-a73f-948d25c788e7'	System	26 Oct 2020 02:15:36
User entered '25 Oct 2020 21:15'	System	26 Oct 2020 02:15:36

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:39:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:25:43

US3922074

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(24)

Generated On: 12 Aug 2021 13:39:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:25:43

US3922074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
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).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	System	19 Oct 2020 13:10:55
User closed query 'Data is required. Please complete.' (Site from System).	Pauline Jackson (b) (4)	19 Oct 2020 13:10:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	(b) (4)	
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	19 Oct 2020 13:10:47
User entered 'Yes (Y)' reason for change: Data Entry Error	System	19 Oct 2020 13:10:47
User opened query 'Data is required. Please complete.' (Site from System).	Pauline Jackson (b) (4)	19 Oct 2020 13:10:47
User entered empty.	(b) (4)	
	System	19 Oct 2020 13:10:35
	Pauline Jackson (b) (4)	19 Oct 2020 13:10:35
	(b) (4)	

US3922074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	Pauline Jackson (b) (4)	19 Oct 2020 13:10:35

US3922074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	Pauline Jackson (b) (4)	19 Oct 2020 13:10:35

US3922074

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	Pauline Jackson (b) (4)	19 Oct 2020 13:10:35

US3922074

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	19 Oct 2020 13:11:04

US3922074

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'I'	System	19 Oct 2020 13:11:04

US3922074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	19 Oct 2020 13:11:21

US3922074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '16 Oct 2020'	Pauline Jackson (b) (4)	19 Oct 2020 13:11:21

US3922074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	19 Oct 2020 13:11:21

US3922074

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Pauline Jackson (b) (4)	19 Oct 2020 13:11:21

US3922074

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	19 Oct 2020 13:11:30

US3922074

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'I'	System	19 Oct 2020 13:11:30

US3922074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	26 Oct 2020 16:34:23

US3922074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '26 Oct 2020'	Pauline Jackson (b) (4)	26 Oct 2020 16:34:23

US3922074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	26 Oct 2020 16:34:23

US3922074

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'subject returned call'	Pauline Jackson (b) (4)	26 Oct 2020 16:34:23

US3922074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	26 Oct 2020 16:34:29

US3922074

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'I'	System	26 Oct 2020 16:34:29

US3922074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	lynn yauch (b) (4)	04 Nov 2020 19:53:00

US3922074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '04 Nov 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:00

US3922074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Clinic (Clinic)'	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:00

US3922074

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered 'VISIT3'	System	04 Nov 2020 19:53:00

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	lynn yauch (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered empty.	System	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	lynn yauch (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	lynn yauch (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered empty.	System	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered empty.	System	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered empty.	System	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	lynn yauch (b) (4)	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered empty.	System	04 Nov 2020 19:53:05

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Mar 2021 08:44:53

US3922074

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Mar 2021 08:44:53

US3922074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	04 Nov 2020 19:54:03
User entered 'No (N)'	(b) (4)	
	lynn yauch (b) (4)	04 Nov 2020 19:53:11
	(b) (4)	

US3922074

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	04 Nov 2020 19:54:03
User entered empty.	(b) (4)	
	lynn yauch (b) (4)	04 Nov 2020 19:53:11
	(b) (4)	

US3922074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	lynn yauch (b) (4)	04 Nov 2020 19:53:39

US3922074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '04 Nov 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:39

US3922074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '10:06'	(b) (4) lynn yauch (b) (4) (b) (4)	04 Nov 2020 19:53:39

US3922074

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered '04 Nov 2020 10:06'	System	04 Nov 2020 19:53:39

US3922074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	lynn yauch (b) (4)	04 Nov 2020 19:54:09

US3922074

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:53
User entered '1'	System	04 Nov 2020 19:54:09

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 64'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-04T17:30:45', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '83712347-1816-4ee8-84d8-6f0810befce4'	System	04 Nov 2020 23:31:05
User entered 'No (N)'	System	04 Nov 2020 23:31:05

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-04T17:30:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '83712347-1816-4ee8-84d8-6f0810befce4'	System	04 Nov 2020 23:31:05
User entered 'No (N)'	System	04 Nov 2020 23:31:05

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-04T17:30:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '83712347-1816-4ee8-84d8-6f0810befce4'	System	04 Nov 2020 23:31:05
User entered '04 Nov 2020 17:30:58'	System	04 Nov 2020 23:31:05

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 71'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-09T17:30:34', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9b423f7b-bcd5-4fe6-99bc-00ef1d920bea'	System	09 Nov 2020 23:30:44
User entered 'No (N)'	System	09 Nov 2020 23:30:44

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-09T17:30:37', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9b423f7b-bcd5-4fe6-99bc-00ef1d920bea'	System	09 Nov 2020 23:30:44
User entered 'No (N)'	System	09 Nov 2020 23:30:44

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-09T17:30:41', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9b423f7b-bcd5-4fe6-99bc-00ef1d920bea'	System	09 Nov 2020 23:30:44
User entered '09 Nov 2020 17:30:41'	System	09 Nov 2020 23:30:44

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered 'Day 78'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-16T17:27:38', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a9144987-0dda-4916-a8af-fd261acb128f'	System	16 Nov 2020 23:27:45
User entered 'No (N)'	System	16 Nov 2020 23:27:45

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-16T17:27:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a9144987-0dda-4916-a8af-fd261acb128f'	System	16 Nov 2020 23:27:45
User entered 'No (N)'	System	16 Nov 2020 23:27:45

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-16T17:27:40', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'a9144987-0dda-4916-a8af-fd261acb128f' User entered '16 Nov 2020 17:27:40'	System	16 Nov 2020 23:27:45
	System	16 Nov 2020 23:27:45

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 20:02:47

US3922074

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:15:22
Data entry locked.	System	02 Sep 2020 20:02:47
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 20:02:47

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (13248247c96bd01c)', Time: '2020-11-20T18:13:26', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e511dda8-be4a-48be-8cf8-87dd2fe59342'	System	21 Nov 2020 00:14:42
User entered 'No (N)'	System	21 Nov 2020 00:14:42

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (13248247c96bd01c)', Time: '2020-11-20T18:13:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e511dda8-be4a-48be-8cf8-87dd2fe59342'	System	21 Nov 2020 00:14:42
User entered 'No (N)'	System	21 Nov 2020 00:14:42

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-20T18:13:33', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e511dda8-be4a-48be-8cf8-87dd2fe59342'	System	21 Nov 2020 00:14:42
User entered '20 Nov 2020 18:13:33'	System	21 Nov 2020 00:14:42

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (13248247c96bd01c)', Time: '2020-11-29T11:23:51', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd2e6f982-82ad-46a1-be23-fdf0ec9de3c6'	System	29 Nov 2020 17:24:01
User entered 'No (N)'	System	29 Nov 2020 17:24:01

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 (13248247c96bd01c)', Time: '2020-11-29T11:23:54', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd2e6f982-82ad-46a1-be23-fdf0ec9de3c6'	System	29 Nov 2020 17:24:01
User entered 'No (N)'	System	29 Nov 2020 17:24:01

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-11-29T11:23:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd2e6f982-82ad-46a1-be23-fdf0ec9de3c6'	System	29 Nov 2020 17:24:01
User entered '29 Nov 2020 11:23:58'	System	29 Nov 2020 17:24:01

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (13248247c96bd01c)', Time: '2020-12-04T09:39:06', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'da637ea9-b6fd-408b-83a6-34c5631929be'	System	04 Dec 2020 15:39:15
User entered 'No (N)'	System	04 Dec 2020 15:39:15

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (13248247c96bd01c)', Time: '2020-12-04T09:39:09', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'da637ea9-b6fd-408b-83a6-34c5631929be'	System	04 Dec 2020 15:39:15
User entered 'No (N)'	System	04 Dec 2020 15:39:15

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-12-04T09:39:13', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'da637ea9-b6fd-408b-83a6-34c5631929be'	System	04 Dec 2020 15:39:15
User entered '04 Dec 2020 09:39:13'	System	04 Dec 2020 15:39:15

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (13248247c96bd01c)', Time: '2020-12-11T11:41:44', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5f2de357-395c-44d9-a4f2-0590cc051a94'	System	11 Dec 2020 17:41:55
User entered 'No (N)'	System	11 Dec 2020 17:41:55

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 (13248247c96bd01c)', Time: '2020-12-11T11:41:46', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5f2de357-395c-44d9-a4f2-0590cc051a94'	System	11 Dec 2020 17:41:55
User entered 'No (N)'	System	11 Dec 2020 17:41:55

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-12-11T11:41:49', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5f2de357-395c-44d9-a4f2-0590cc051a94'	System	11 Dec 2020 17:41:55
User entered '11 Dec 2020 11:41:49'	System	11 Dec 2020 17:41:55

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (13248247c96bd01c)', Time: '2020-12-18T10:46:55', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5749aafb-0818-4499-a19f-57bf34dde40b'	System	18 Dec 2020 16:47:04
User entered 'No (N)'	System	18 Dec 2020 16:47:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (13248247c96bd01c)', Time: '2020-12-18T10:46:58', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5749aafb-0818-4499-a19f-57bf34dde40b'	System	18 Dec 2020 16:47:04
User entered 'No (N)'	System	18 Dec 2020 16:47:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (13248247c96bd01c)', Time: '2020-12-18T10:47:01', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '5749aafb-0818-4499-a19f-57bf34dde40b'	System	18 Dec 2020 16:47:04
User entered '18 Dec 2020 10:47:01'	System	18 Dec 2020 16:47:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2020-12-28T16:34:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '937e2714-e917-4c6b-bb7a-84402a74dd87'	System	28 Dec 2020 22:34:31
User entered 'No (N)'	System	28 Dec 2020 22:34:31

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2020-12-28T16:34:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '937e2714-e917-4c6b-bb7a-84402a74dd87'	System	28 Dec 2020 22:34:31
User entered 'No (N)'	System	28 Dec 2020 22:34:31

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2020-12-28T16:34:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '937e2714-e917-4c6b-bb7a-84402a74dd87'	System	28 Dec 2020 22:34:31
User entered '28 Dec 2020 16:34:27'	System	28 Dec 2020 22:34:31

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-01-03T20:52:14', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd4568dae-0570-4107-9093-09281bebdb1c'	System	04 Jan 2021 02:52:22
User entered 'No (N)'	System	04 Jan 2021 02:52:22

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-01-03T20:52:17', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd4568dae-0570-4107-9093-09281bebdb1c'	System	04 Jan 2021 02:52:22
User entered 'No (N)'	System	04 Jan 2021 02:52:22

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-01-03T20:52:20', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd4568dae-0570-4107-9093-09281bebdb1c'	System	04 Jan 2021 02:52:22
User entered '03 Jan 2021 20:52:20'	System	04 Jan 2021 02:52:22

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-01-08T08:56:18', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6555a1c1-40de-4754-9789-2301057e0b08'	System	08 Jan 2021 14:56:31
User entered 'No (N)'	System	08 Jan 2021 14:56:31

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-01-08T08:56:21', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6555a1c1-40de-4754-9789-2301057e0b08'	System	08 Jan 2021 14:56:31
User entered 'No (N)'	System	08 Jan 2021 14:56:31

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-01-08T08:56:25', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '6555a1c1-40de-4754-9789-2301057e0b08'	System	08 Jan 2021 14:56:31
User entered '08 Jan 2021 08:56:25'	System	08 Jan 2021 14:56:31

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-01-15T00:30:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '17184705-717f-478c-8f75-3c7a8b1073d6'	System	15 Jan 2021 06:30:15
User entered 'No (N)'	System	15 Jan 2021 06:30:15

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-01-15T00:30:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '17184705-717f-478c-8f75-3c7a8b1073d6'	System	15 Jan 2021 06:30:15
User entered 'No (N)'	System	15 Jan 2021 06:30:15

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-01-15T00:30:11', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '17184705-717f-478c-8f75-3c7a8b1073d6'	System	15 Jan 2021 06:30:15
User entered '15 Jan 2021 00:30:11'	System	15 Jan 2021 06:30:15

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-01-26T09:56:12', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ae7a5a14-d0a5-4720-b2c1-7de78899f983'	System	26 Jan 2021 15:57:26
User entered 'No (N)'	System	26 Jan 2021 15:57:26

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-01-26T09:56:17', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ae7a5a14-d0a5-4720-b2c1-7de78899f983'	System	26 Jan 2021 15:57:26
User entered 'No (N)'	System	26 Jan 2021 15:57:26

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-01-26T09:56:20', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ae7a5a14-d0a5-4720-b2c1-7de78899f983'	System	26 Jan 2021 15:57:26
User entered '26 Jan 2021 09:56:20'	System	26 Jan 2021 15:57:26

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-01-29T09:24:03', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dfb0b6e3-a4bd-4132-b769-2d8784b9e5e8'	System	29 Jan 2021 15:24:14
User entered 'No (N)'	System	29 Jan 2021 15:24:14

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-01-29T09:24:07', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dfb0b6e3-a4bd-4132-b769-2d8784b9e5e8'	System	29 Jan 2021 15:24:14
User entered 'No (N)'	System	29 Jan 2021 15:24:14

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-01-29T09:24:10', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'dfb0b6e3-a4bd-4132-b769-2d8784b9e5e8'	System	29 Jan 2021 15:24:14
User entered '29 Jan 2021 09:24:10'	System	29 Jan 2021 15:24:14

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-02-06T17:48:47', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '54b0c26f-8314-4fdd-bda4-722773187151'	System	06 Feb 2021 23:48:56
User entered 'No (N)'	System	06 Feb 2021 23:48:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-02-06T17:48:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '54b0c26f-8314-4fdd-bda4-722773187151'	System	06 Feb 2021 23:48:56
User entered 'No (N)'	System	06 Feb 2021 23:48:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-02-06T17:48:53', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '54b0c26f-8314-4fdd-bda4-722773187151'	System	06 Feb 2021 23:48:56
User entered '06 Feb 2021 17:48:53'	System	06 Feb 2021 23:48:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-02-13T15:31:50', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e5b5ba49-2a9a-4f45-ba32-e88c204a0068'	System	13 Feb 2021 21:32:04
User entered 'No (N)'	System	13 Feb 2021 21:32:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-02-13T15:31:55', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e5b5ba49-2a9a-4f45-ba32-e88c204a0068'	System	13 Feb 2021 21:32:04
User entered 'No (N)'	System	13 Feb 2021 21:32:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-02-13T15:31:57', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'e5b5ba49-2a9a-4f45-ba32-e88c204a0068'	System	13 Feb 2021 21:32:04
User entered '13 Feb 2021 15:31:57'	System	13 Feb 2021 21:32:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-02-19T19:06:23', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9e494302-093e-444c-a930-e5a0b13bc0b3'	System	20 Feb 2021 01:06:39
User entered 'No (N)'	System	20 Feb 2021 01:06:39

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-02-19T19:06:27', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9e494302-093e-444c-a930-e5a0b13bc0b3'	System	20 Feb 2021 01:06:39
User entered 'No (N)'	System	20 Feb 2021 01:06:39

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-02-19T19:06:30', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '9e494302-093e-444c-a930-e5a0b13bc0b3'	System	20 Feb 2021 01:06:39
User entered '19 Feb 2021 19:06:30'	System	20 Feb 2021 01:06:39

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-02-26T22:41:44-06:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc6b1de9-6af7-4a91-825d-c2d4a82f979e'	System	27 Feb 2021 04:41:53
User entered 'No (N)'	System	27 Feb 2021 04:41:53

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-02-26T22:41:47-06:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc6b1de9-6af7-4a91-825d-c2d4a82f979e'	System	27 Feb 2021 04:41:53
User entered 'No (N)'	System	27 Feb 2021 04:41:53

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-02-26T22:41:49-06:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc6b1de9-6af7-4a91-825d-c2d4a82f979e'	System	27 Feb 2021 04:41:53
User entered '26 Feb 2021 22:41:49'	System	27 Feb 2021 04:41:53

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-03-08T22:25:16-06:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ff76eac2-657b-4ac0-9b5e-17280ff35cb0'	System	09 Mar 2021 04:25:23
User entered 'No (N)'	System	09 Mar 2021 04:25:23

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-03-08T22:25:18-06:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ff76eac2-657b-4ac0-9b5e-17280ff35cb0'	System	09 Mar 2021 04:25:23
User entered 'No (N)'	System	09 Mar 2021 04:25:23

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-03-08T22:25:20-06:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'ff76eac2-657b-4ac0-9b5e-17280ff35cb0'	System	09 Mar 2021 04:25:23
User entered '08 Mar 2021 22:25:20'	System	09 Mar 2021 04:25:23

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-03-12T10:47:16-07:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd908bf1e-d25d-4185-b6c7-f715ed4917be'	System	12 Mar 2021 17:47:27
User entered 'No (N)'	System	12 Mar 2021 17:47:27

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-03-12T10:47:17-07:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd908bf1e-d25d-4185-b6c7-f715ed4917be'	System	12 Mar 2021 17:47:27
User entered 'No (N)'	System	12 Mar 2021 17:47:27

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-03-12T10:47:24-07:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'd908bf1e-d25d-4185-b6c7-f715ed4917be' User entered '12 Mar 2021 10:47:24'	System	12 Mar 2021 17:47:27
	System	12 Mar 2021 17:47:27

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-03-19T08:33:11-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '0fc58ecc-4a95-4ecc-8b93-c8d2e0d3ba24'	System	19 Mar 2021 13:33:35
User entered 'No (N)'	System	19 Mar 2021 13:33:35

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-03-19T08:33:20-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '0fc58ecc-4a95-4ecc-8b93-c8d2e0d3ba24'	System	19 Mar 2021 13:33:35
User entered 'No (N)'	System	19 Mar 2021 13:33:35

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-03-19T08:33:29-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '0fc58ecc-4a95-4ecc-8b93-c8d2e0d3ba24'	System	19 Mar 2021 13:33:35
User entered '19 Mar 2021 08:33:29'	System	19 Mar 2021 13:33:35

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-03-26T22:26:04-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b99357a-f874-4689-a41d-d1bb453b30d4'	System	27 Mar 2021 03:30:04
User entered 'No (N)'	System	27 Mar 2021 03:30:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-03-26T22:26:06-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b99357a-f874-4689-a41d-d1bb453b30d4'	System	27 Mar 2021 03:30:04
User entered 'No (N)'	System	27 Mar 2021 03:30:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-03-26T22:26:09-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3b99357a-f874-4689-a41d-d1bb453b30d4'	System	27 Mar 2021 03:30:04
User entered '26 Mar 2021 22:26:09'	System	27 Mar 2021 03:30:04

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-04-02T14:45:36-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '64e519da-7e3c-453a-9b41-ab8d79ff92e2'	System	02 Apr 2021 19:45:45
User entered 'No (N)'	System	02 Apr 2021 19:45:45

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-04-02T14:45:39-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '64e519da-7e3c-453a-9b41-ab8d79ff92e2'	System	02 Apr 2021 19:45:45
User entered 'No (N)'	System	02 Apr 2021 19:45:45

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-04-02T14:45:42-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '64e519da-7e3c-453a-9b41-ab8d79ff92e2'	System	02 Apr 2021 19:45:45
User entered '02 Apr 2021 14:45:42'	System	02 Apr 2021 19:45:45

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-04-09T12:04:27-04:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172d05e-1001-4b23-92b9-5e56ca4ca9f8'	System	09 Apr 2021 16:09:50
User entered 'No (N)'	System	09 Apr 2021 16:09:50

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-04-09T12:04:30-04:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172d05e-1001-4b23-92b9-5e56ca4ca9f8'	System	09 Apr 2021 16:09:50
User entered 'No (N)'	System	09 Apr 2021 16:09:50

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-04-09T12:04:32-04:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '3172d05e-1001-4b23-92b9-5e56ca4ca9f8'	System	09 Apr 2021 16:09:50
User entered '09 Apr 2021 12:04:32'	System	09 Apr 2021 16:09:50

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-04-16T09:01:07-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '16f60804-4afe-4eeb-b446-417672e65389'	System	16 Apr 2021 14:01:16
User entered 'No (N)'	System	16 Apr 2021 14:01:16

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-04-16T09:01:11-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '16f60804-4afe-4eeb-b446-417672e65389'	System	16 Apr 2021 14:01:16
User entered 'No (N)'	System	16 Apr 2021 14:01:16

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-04-16T09:01:13-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '16f60804-4afe-4eeb-b446-417672e65389'	System	16 Apr 2021 14:01:16
User entered '16 Apr 2021 09:01:13'	System	16 Apr 2021 14:01:16

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-04-23T12:36:19-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c61dae5a-bd7e-4450-acb2-012a68b4b58c'	System	23 Apr 2021 17:36:28
User entered 'No (N)'	System	23 Apr 2021 17:36:28

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-04-23T12:36:22-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c61dae5a-bd7e-4450-acb2-012a68b4b58c'	System	23 Apr 2021 17:36:28
User entered 'No (N)'	System	23 Apr 2021 17:36:28

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-04-23T12:36:24-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'c61dae5a-bd7e-4450-acb2-012a68b4b58c' User entered '23 Apr 2021 12:36:24'	System	23 Apr 2021 17:36:28
	System	23 Apr 2021 17:36:28

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[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 (f2d415d0aa4418f6)', Time: '2021-04-30T09:35:07-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '0fee8e06-169f-42de-ad10-fa0b8f51125b' User entered 'No (N)'	System	30 Apr 2021 14:35:17
	System	30 Apr 2021 14:35:17

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

Have you been exposed to someone with 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 (f2d415d0aa4418f6)', Time: '2021-04-30T09:35:09-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '0fee8e06-169f-42de-ad10-fa0b8f51125b'	System	30 Apr 2021 14:35:17
User entered 'No (N)'	System	30 Apr 2021 14:35:17

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-04-30T09:35:11-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: '0fee8e06-169f-42de-ad10-fa0b8f51125b' User entered '30 Apr 2021 09:35:11'	System	30 Apr 2021 14:35:17
	System	30 Apr 2021 14:35:17

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:39:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:39:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:39:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:39:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:39:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:39:56

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:39:56

US3922074

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:39:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:39:56
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:39:56

US3922074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:39:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:44:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-03-02T00:14:45-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc7a3150-db64-402b-9ae2-8e0c254fbf88'	System	02 Mar 2021 05:14:54
User entered 'No (N)'	System	02 Mar 2021 05:14:54

US3922074

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:39:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 23:44:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f2d415d0aa4418f6)', Time: '2021-03-02T00:14:51-05:00', User OID: 'PatientReportedOutcome (US3922074)', ODM File OID: 'cc7a3150-db64-402b-9ae2-8e0c254fbf88'	System	02 Mar 2021 05:14:54
User entered '02 Mar 2021 00:14:51'	System	02 Mar 2021 05:14:54

US3922074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	24 Nov 2020 21:19:16

US3922074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered '24 Nov 2020'	Pauline Jackson (b) (4)	24 Nov 2020 21:19:16

US3922074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	24 Nov 2020 21:19:16

US3922074

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered empty.	Pauline Jackson (b) (4)	24 Nov 2020 21:19:16

US3922074

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:35
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	24 Nov 2020 21:19:36

US3922074

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:44:47
User entered 'I'	System	24 Nov 2020 21:19:36

US3922074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	28 Dec 2020 15:35:07

US3922074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '28 Dec 2020'	Pauline Jackson (b) (4)	28 Dec 2020 15:35:07

US3922074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	28 Dec 2020 15:35:07

US3922074

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	Pauline Jackson (b) (4)	28 Dec 2020 15:35:07

US3922074

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	28 Dec 2020 15:35:12

US3922074

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User entered '1'	System	28 Dec 2020 15:35:12

US3922074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	28 Jan 2021 21:32:01

US3922074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '28 Jan 2021'	Jennifer Ruiz (b) (4)	28 Jan 2021 21:32:01

US3922074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	28 Jan 2021 21:32:01

US3922074

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	Jennifer Ruiz (b) (4)	28 Jan 2021 21:32:01

US3922074

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	28 Jan 2021 21:32:13

US3922074

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User entered '1'	System	28 Jan 2021 21:32:13

US3922074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 14:15:08
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	01 Mar 2021 18:55:18

US3922074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 14:15:08
User entered '1 Mar 2021'	Jennifer Ruiz (b) (4)	01 Mar 2021 18:55:18

US3922074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 14:15:08
User entered 'Contact Made (CONTACT MADE)'	Jennifer Ruiz (b) (4)	01 Mar 2021 18:55:18

US3922074

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 14:15:08
User entered empty.	Jennifer Ruiz (b) (4)	01 Mar 2021 18:55:18

US3922074

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User signature succeeded.	Michele Reynolds (b) (4)	02 Mar 2021 14:15:08
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	01 Mar 2021 18:55:21

US3922074

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 05:02:11
User entered 'I'	System	01 Mar 2021 18:55:21

US3922074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered 'Yes (Y)'	Pamela Echols (b) (4)	24 Mar 2021 14:53:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered '18 Mar 2021'	Pamela Echols (b) (4)	24 Mar 2021 14:53:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[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 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered 'Clinic (Clinic)'	Pamela Echols (b) (4)	24 Mar 2021 14:53:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered 'VISIT4'	System	24 Mar 2021 14:53:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered 'No (N)'	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered empty.	System	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered empty.	System	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered empty.	System	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered empty.	System	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	30 Mar 2021 22:06:29
User entered empty.	Jacklyn Newton (b) (4)	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered empty.	System	30 Mar 2021 18:08:06

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:36:56

US3922074

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:39:26

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 20:36:56

US3922074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered 'No (N)'	Pamela Echols (b) (4)	24 Mar 2021 14:55:04

US3922074

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:39:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered empty.	Pamela Echols (b) (4)	24 Mar 2021 14:55:04

US3922074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered 'Yes (Y)'	Pamela Echols (b) (4)	24 Mar 2021 14:55:42

US3922074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered '18 Mar 2021'	Pamela Echols (b) (4)	24 Mar 2021 14:55:42

US3922074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered '10:40'	Pamela Echols (b) (4)	24 Mar 2021 14:55:42

US3922074

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered '18 Mar 2021 10:40'	System	24 Mar 2021 14:55:42

US3922074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User signature succeeded.	Michele Reynolds (b) (4)	24 Mar 2021 16:45:14
User entered 'Yes (Y)'	Pamela Echols (b) (4)	24 Mar 2021 14:55:50

US3922074

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:36:56
User entered 'I'	System	24 Mar 2021 14:55:50

US3922074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	03 May 2021 22:11:16
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	30 Apr 2021 17:32:36
	(b) (4)	

US3922074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	03 May 2021 22:11:16
	(b) (4)	
User entered '30 Apr 2021'	Jennifer Ruiz (b) (4)	30 Apr 2021 17:32:36
	(b) (4)	

US3922074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	03 May 2021 22:11:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	30 Apr 2021 17:32:36

US3922074

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:39:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	03 May 2021 22:11:16
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	30 Apr 2021 17:32:36
	(b) (4)	

US3922074

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	03 May 2021 22:11:16
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	30 Apr 2021 17:32:39
	(b) (4)	

US3922074

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:39:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 17:32:39

US3922074

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

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:30

US3922074

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

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '22 Jan 2021'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:30

US3922074

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

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Clinic (Clinic)'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:30

US3922074

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

Form: Visit Date

Generated On: 12 Aug 2021 13:39:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 20:10:30

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '22 Jan 2021'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 15:03:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:22:28

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
User entered 'Amendment 6 or later (Amendment 6 or later)'	Pamela Echols (b) (4)	10 Mar 2021 15:03:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:22:28

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '22 Jan 2021'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'mRNA-1273 (mRNA-1273)'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'mRNA-1273 (mRNA-1273)'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'mRNA-1273 (mRNA-1273)'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'No (N)'	Pauline Jackson (b) (4)	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User entered empty.	System	22 Jan 2021 20:10:47

US3922074

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

Form: Unblinding

Generated On: 12 Aug 2021 13:39:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User entered empty.	System	22 Jan 2021 20:10:47

US3922074

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	22 Jan 2021 20:11:10

US3922074

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '22 Jan 2021'	Pauline Jackson (b) (4)	22 Jan 2021 20:11:10

US3922074

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '09:49'	Pauline Jackson (b) (4)	22 Jan 2021 20:11:10

US3922074

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:39:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User entered '22 Jan 2021 09:49'	System	22 Jan 2021 20:11:10

US3922074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:39:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	22 Jan 2021 20:11:22

US3922074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:39:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '22 Jan 2021'	Pauline Jackson (b) (4)	22 Jan 2021 20:11:22

US3922074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:39:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '10:06'	Pauline Jackson (b) (4)	22 Jan 2021 20:11:22

US3922074

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:39:26

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:59:53
User entered '22 Jan 2021 10:06'	System	22 Jan 2021 20:11:22

US3922074

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:39:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:29:07
User signature succeeded.	Michele Reynolds (b) (4)	06 Apr 2021 13:36:06
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 09SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 08:11:03
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 09SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'recorded as Solicited Adverse Event. updated per query' (Site from DM).	Jennifer Ruiz (b) (4) (b) (4)	02 Apr 2021 21:46:14
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (DAY 8 on 09SEP2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 03:57:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	07 Dec 2020 18:24:47
User entered 'No (N)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:47:43

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 10:31:49

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical radiculopathy, LLT: Cervical radiculopathy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 18:28:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:28:12
Data point term sent to Coder	System	07 Dec 2020 18:26:51
User entered 'Worsening cervical radiculopathy'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '04 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User entered empty.	System	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	13 Jan 2021 14:57:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '25 Nov 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	13 Jan 2021 14:57:56
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User entered empty.	System	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User closed query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 09:10:23
Query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	30 Dec 2020 18:58:00
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 18:57:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Dec 2020 18:57:54
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	30 Dec 2020 18:57:54
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 17:36:49
User entered empty; reason for change Data Entry Error	Pamela Echols (b) (4) (b) (4)	29 Dec 2020 17:36:49
User opened query 'Per CDM: Action taken with investigational product is 'None', however, per CCGs Version 2.0 page 35, 'Not Applicable' should be recorded if the Adverse Event started after last dose of investigational product. Please clarify and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:10:47
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 18:26:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Dec 2020 18:26:45
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 18:26:45
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6) [REDACTED]	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User closed query 'Per CDM : Please note that 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. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 08:23:43
Query 'Per CDM : Please note that 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. Thank you.' answered with 'CM # 7 matches this AE' (Site from DM).	Pauline Jackson (b) (4)	22 Jan 2021 19:57:25
User opened query 'Per CDM : Please note that 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. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 18:43:25
User entered 'I'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	lynn yauch (b) (4)	13 Jan 2021 14:57:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User entered '0'	System	07 Dec 2020 18:26:22

US3922074

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:49
User entered '0'	System	07 Dec 2020 18:26:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 10:31:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 19:47:44
Data point term sent to Coder	(b) (4)	
Coding entries removed.	Coder Import (b) (4)	02 Apr 2021 19:47:44
User entered 'Worsening of DEPRESSION' reason for change: Data Entry Error	(b) (4)	
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)	02 Apr 2021 19:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	02 Apr 2021 19:46:08
Coding entries removed.	Jennifer Ruiz (b) (4)	02 Apr 2021 19:46:07
User entered 'Worsening of DEPRESSION' reason for change: Data Entry Error	(b) (4)	
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.	Jennifer Ruiz (b) (4)	02 Apr 2021 19:46:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	02 Apr 2021 18:06:44
Coding entries removed.	(b) (4)	
Signature has been broken.	System	02 Apr 2021 18:05:35
User entered 'Depression' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Apr 2021 18:04:48
User signature succeeded.	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	lynn yauch (b) (4)	02 Apr 2021 18:04:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	lynn yauch (b) (4)	02 Apr 2021 18:04:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	lynn yauch (b) (4)	02 Apr 2021 18:04:48
User entered 'Insomnia'	(b) (4)	
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 14:47:52
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 14:47:52
Data point term sent to Coder	(b) (4)	
User entered 'Insomnia'	Coder Import (b) (4)	10 Mar 2021 14:32:53
User signature succeeded.	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 14:32:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	10 Mar 2021 14:32:06
User entered 'Insomnia'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'No (N)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'No (N)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	System	06 Apr 2021 20:16:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:54
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	02 Apr 2021 20:39:40
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	02 Apr 2021 20:39:40
User entered 'UN Nov 2020' (non-conformant).	Jennifer Ruiz (b) (4)	02 Apr 2021 20:39:40
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4)	02 Apr 2021 19:45:19
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	02 Apr 2021 19:45:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Apr 2021 19:45:19
User entered '15 Mar 2020' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 19:45:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	02 Apr 2021 18:05:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Apr 2021 18:05:01
User entered 'UN Nov 2020' (non-conformant).	lynn yauch (b) (4)	02 Apr 2021 18:05:01
	(b) (4)	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Data entered is non-conformant. Please correct.' (Site from System). Signature has been broken.	System lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:04:48 02 Apr 2021 18:04:48
User entered 'un Nov 2021' (non-conformant).	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:04:48
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	11 Mar 2021 16:31:19
User entered '15 Feb 2021'	Pamela Echols (b) (4) (b) (4)	10 Mar 2021 14:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'Yes (Y)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:31:35

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'No (N)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(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.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered 'None (NONE)'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 07:35:51
Query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' answered with 'see concomitant medication #10' (Site from DM).	Jennifer Ruiz (b) (4) (b) (4)	02 Apr 2021 19:47:21
User opened query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:08:36
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	11 Mar 2021 16:31:19
User entered 'I'	Pamela Echols (b) (4) (b) (4)	10 Mar 2021 14:31:35

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered '0'	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Mar 2021 14:32:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	10 Mar 2021 14:32:09
User opened query 'Data is required. Please complete.' (Site from System).	Pamela Echols (b) (4)	10 Mar 2021 14:32:09
User entered empty.	(b) (4)	
	System	10 Mar 2021 14:31:35
	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 16:31:19
	(b) (4)	
User entered empty.	Pamela Echols (b) (4)	10 Mar 2021 14:31:35
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 14:31:35

US3922074

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:39:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 14:31:35

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User coded data point as SOC: Psychiatric disorders, HLT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Apr 2021 18:19:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Apr 2021 18:19:22
Data point term sent to Coder	System	02 Apr 2021 18:15:57
User entered 'bipolar disorder'	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '19 Jan 2021'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

None

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	02 Apr 2021 18:15:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Apr 2021 18:15:20
User entered '0'	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Apr 2021 18:15:28
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:15:20
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:39:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 18:15:20

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Hypoacusis, LLT: Partial hearing loss - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Apr 2021 12:47:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 12:47:49
Data point term sent to Coder	(b) (4) System	02 Apr 2021 18:18:00
User entered 'partial hearing loss right'	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:17:04

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	02 Apr 2021 20:15:23
User entered '12 Dec 2020' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 20:15:23
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Apr 2021 18:17:04
User entered 'un Nov 2020' (non-conformant).	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:17:04

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:17:04

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'I'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:17:04

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:17:04
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 18:17:04

US3922074

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:39:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 18:17:04

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 10:31:56

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Apr 2021 18:20:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 18:20:54
Data point term sent to Coder	System	02 Apr 2021 18:19:00
User entered 'tinnitus right'	lynn yauch (b) (4)	02 Apr 2021 18:18:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Yes (Y)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '12 Dec 2020' reason for change: Data Entry Error	System	02 Apr 2021 20:15:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Jennifer Ruiz (b) (4)	02 Apr 2021 20:15:45
User entered 'un Nov 2020' (non-conformant).	(b) (4)	
	System	02 Apr 2021 18:18:25
	lynn yauch (b) (4)	02 Apr 2021 18:18:25
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User entered empty.	System	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 21:45:33
User entered 'Yes (Y)'	lynn yauch (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '19 Mar 2021' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 21:45:33
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User entered empty.	System	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'I'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 21:45:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	lynn yauch (b) (4)	02 Apr 2021 18:18:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User entered '0'	System	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:31:56
User entered '1'	System	02 Apr 2021 18:18:25

US3922074

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 10:31:56

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 18:20:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 18:20:55
Data point term sent to Coder	System	02 Apr 2021 18:20:03
User entered 'insomnia'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '15 Feb 2021'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:19:40

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 18:19:40

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:19:40

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Related (NOT RELATED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:19:40

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '1'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:19:40

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:19:40
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 18:19:40

US3922074

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:39:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 18:19:40

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:24:49

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:35:46
Data point term sent to Coder	System	02 Apr 2021 20:34:30
User entered 'Fatigue'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Jennifer Ruiz (b) (4)	02 Apr 2021 20:34:00
User entered '9 Sep 2020'	(b) (4)	
	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44
	(b) (4)	

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User entered empty.	System	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '10 Sep 2020'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User entered empty.	System	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'No (N)'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

US3922074

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	29 Apr 2021 15:34:03
User closed query 'Per MM, this event is captured as a solicited event, however it is captured as not related. Please review and update, as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 05:17:30
Query 'Per MM, this event is captured as a solicited event, however it is captured as not related. Please review and update, as appropriate' answered with 'updated per PI review' (Site from DM).	lynn yauch (b) (4) (b) (4)	27 Apr 2021 13:52:34
Signature has been broken.	lynn yauch (b) (4) (b) (4)	27 Apr 2021 13:51:15
User entered 'Related (RELATED)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	27 Apr 2021 13:51:15
User opened query 'Per MM, this event is captured as a solicited event, however it is captured as not related. Please review and update, as appropriate' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 09:41:04
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	08 Apr 2021 19:16:13
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 14:55:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 14:55:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	08 Apr 2021 14:55:34
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 20:33:44
User entered empty.	Jennifer Ruiz (b) (4) (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Apr 2021 14:55:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 14:55:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	lynn yauch (b) (4)	08 Apr 2021 14:55:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Apr 2021 20:33:44
User entered empty.	System	02 Apr 2021 20:33:44
	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Apr 2021 14:55:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 14:55:34
User entered 'None (NONE)' reason for change: Data Entry Error	lynn yauch (b) (4)	08 Apr 2021 14:55:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Apr 2021 20:33:44
User entered empty.	System	02 Apr 2021 20:33:44
	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'I'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered '0'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[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 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:13
User entered empty.	Jennifer Ruiz (b) (4)	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User entered '0'	System	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:24:49
User entered '0'	System	02 Apr 2021 20:33:44

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 12 Aug 2021 13:39:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:24:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:39:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:29:07
User signature succeeded.	Michele Reynolds (b) (4)	12 Apr 2021 15:33:32
User closed query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'update CM per query' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:39:49
User opened query 'Per DM CLR: Per Diary Dose 2 Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	lynn yauch (b) (4) (b) (4)	08 Apr 2021 15:00:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 17:22:36
	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:50:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Per CDM: Re-Query: Per query response on Diary Dose 2, Temperature Timepoint DAYS 2 to 23, it was indicated as "participant contacted and documented in source. medication added to con med eCRF". Please confirm the corresponding medication details recorded in this Prior/Concomitant and Vaccination eCRF page. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 11:33:52
Query 'Per CDM: Re-Query: Per query response on Diary Dose 2, Temperature Timepoint DAYS 2 to 23, it was indicated as "participant contacted and documented in source. medication added to con med eCRF". Please confirm the corresponding medication details recorded in this Prior/Concomitant and Vaccination eCRF page. Thank you.' answered with 'participant took already prescribed methocarbamol (used for cervical radiculopathy) on dates documented in diary dose' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	28 Oct 2020 14:22:18
User opened query 'Per CDM: Re-Query: Per query response on Diary Dose 2, Temperature Timepoint DAYS 2 to 23, it was indicated as "participant contacted and documented in source. medication added to con med eCRF". Please confirm the corresponding medication details recorded in this Prior/Concomitant and Vaccination eCRF page. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:51:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:52:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:52:52
Data point term sent to Coder	System	04 Sep 2020 20:51:46
User entered 'losartan'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:51:18

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'hypertension'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '50'	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'once daily (QD)'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Oral (ORAL)'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'un UNK 2013'	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:51:18
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:51:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:51:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:51:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 20:53:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:53:55
Data point term sent to Coder	System	04 Sep 2020 20:52:48
User entered 'hydroxyzine'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:52:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'seasonal allergies'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '25'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'as needed (PRN)'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Oral (ORAL)'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'un UNK 2015'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:52:23
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:52:23

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:52:23

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:52:23

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 20:54:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 20:54:42
Data point term sent to Coder	System	04 Sep 2020 20:53:49
User entered 'testosterone cypionate'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:53:26

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
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)	21 Nov 2020 15:04:57
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 'updated MH' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:15:34
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)	09 Nov 2020 08:25:59
User entered 'low testosterone'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:53:26

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please review if the specific dose can be provided (Dose per administration = 100 or 200, Dose Unit = Other, Specify = mg/mL). Update if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 15:04:55
Query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please review if the specific dose can be provided (Dose per administration = 100 or 200, Dose Unit = Other, Specify = mg/mL). Update if applicable.' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:50:10
User entered '200' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:50:04
User opened query 'Per DM CLR: Please note, the dosage administered cannot be verified as entered as more than one formulation is available for this medication. Please review if the specific dose can be provided (Dose per administration = 100 or 200, Dose Unit = Other, Specify = mg/mL). Update if applicable.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:26:27
User entered '1'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:53:26

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	11 Nov 2020 21:50:22
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	11 Nov 2020 21:50:04
User entered 'mg (mg)' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	11 Nov 2020 21:50:04
User entered 'Other (OTHER)'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:53:26

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty; reason for change Data Entry Error	Pauline Jackson (b) (4)	11 Nov 2020 21:50:22
	(b) (4)	
User entered 'injection'	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'every month (QM)'	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'un UNK 2016'	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:53:26
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:53:26

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:53:26

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '802 (802)'	System	04 Sep 2020 20:53:26

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: INDOMETACIN, PRODUCTSYNONYM: INDOMETHACIN [INDOMETACIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 20:58:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 20:58:41
Data point term sent to Coder	System	04 Sep 2020 20:54:50
User entered 'indomethacin'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:54:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'intermittent headache'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '75'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'as needed (PRN)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Oral (ORAL)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'un Oct 2019'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:54:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:54:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 20:54:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 21:11:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:11:43
Data point term sent to Coder	System	04 Sep 2020 20:55:51
User entered 'atorvastatin'	Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:54:55

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'hyperlipidemnia'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '10'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'once daily (QD)'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Oral (ORAL)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'un UNK 2012'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:54:55
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:54:55

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:54:55

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:54:55

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Apr 2021 18:11:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 18:11:34
Data point term sent to Coder Coding entries removed.	System lynn yauch (b) (4)	02 Apr 2021 18:10:49 02 Apr 2021 18:10:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:06:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:06:55
Data point term sent to Coder User entered 'pantoprazole'	System Cristina Puig (b) (4) (b) (4)	04 Sep 2020 20:55:51 04 Sep 2020 20:55:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'HEartburn' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Apr 2021 18:10:10
	(b) (4)	
User entered 'heratburn'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '40'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'once daily (QD)'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Oral (ORAL)'	(b) (4) Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'un UNK 2013'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:55:18
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:55:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:55:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 20:55:18

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 15:07:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:07:36
Data point term sent to Coder	System	27 Oct 2020 15:02:36
User entered 'Methocarbamol'	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)'	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'cervical radiculopathy'	(b) (4) Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '500'	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'mg (mg)'	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'as needed (PRN)'	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Oral (ORAL)'	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN UNK 2019' reason for change: Data Entry Error	System	27 Oct 2020 15:03:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Pauline Jackson (b) (4)	27 Oct 2020 15:03:59
User entered 'UN 2019' (non-conformant).	(b) (4)	
User entered 'un Jul 2020'	System	27 Oct 2020 15:03:52
	Pauline Jackson (b) (4)	27 Oct 2020 15:03:52
	(b) (4)	
	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '0'	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	13 Jan 2021 14:58:57
User entered 'Yes (Y)'	(b) (4)	
	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '25 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	lynn yauch (b) (4)	13 Jan 2021 14:58:57
User entered empty.	(b) (4)	
	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)'	Pauline Jackson (b) (4)	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User entered empty.	System	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User entered empty.	System	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:21
User entered empty.	System	27 Oct 2020 15:01:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Dec 2020 18:13:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:13:54
Data point term sent to Coder	System	07 Dec 2020 18:12:50
User entered 'Gabapentin'	(b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'cervical radiculopathy'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '800'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '03 Nov 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Jan 2021 14:59:30
User entered 'Yes (Y)'	lynn yauch (b) (4)	07 Dec 2020 18:12:36
	(b) (4)	
	(b) (4), (b) (6)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '25 Nov 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	13 Jan 2021 14:59:30
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User entered '3'	System	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User entered '1'	System	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:33
User entered '804 (804)'	System	07 Dec 2020 18:12:36

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
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.	(b) (4) Coder Import (b) (4)	21 Dec 2020 21:33:13
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 Dec 2020 21:33:13
Data point term sent to Coder	System	21 Dec 2020 14:21:13
Datapoint queued for coding (5198461).	System	21 Dec 2020 14:20:32
User entered 'Flu vaccine'	(b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'flu prophylaxis'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '0.5'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '29 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User entered empty.	System	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User entered empty.	System	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:39
User entered empty.	System	07 Dec 2020 18:14:39

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 19:48:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 19:48:48
Data point term sent to Coder Coding entries removed.	System Jennifer Ruiz (b) (4)	02 Apr 2021 19:47:11 02 Apr 2021 19:46:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 18:10:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Apr 2021 18:10:32
Data point term sent to Coder Coding entries removed.	System lynn yauch (b) (4)	02 Apr 2021 18:09:48 02 Apr 2021 18:09:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 15:02:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Jan 2021 15:02:01
Data point term sent to Coder User entered 'abilify'	System lynn yauch (b) (4)	13 Jan 2021 15:01:13 13 Jan 2021 15:00:53

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 07:39:37
User entered 'AE#2 (Worsening of DEPRESSION)' reason for change: Data Entry Error	Jennifer Ruiz (b) (4) (b) (4)	02 Apr 2021 19:46:36
Query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:09:41
User entered 'AE#2 DEPRESSION' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:09:17
User opened query 'Per DM CLR: Please note there is no AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:43:31
User entered 'depression(AE #2)'	lynn yauch (b) (4) (b) (4)	13 Jan 2021 15:00:53

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '5'	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'once daily (QD)'	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '15 Dec 2020'	(b) (4) lynn yauch (b) (4) (b) (4)	13 Jan 2021 15:00:53

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	13 Jan 2021 15:00:53
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:00:53

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 15:00:53

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Jan 2021 15:00:53

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: INDOLE DERIVATIVES, PRODUCT: LURASIDONE HYDROCHLORIDE, PRODUCTSYNONYM: LATUDA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Apr 2021 18:35:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 18:35:23
Data point term sent to Coder	System	02 Apr 2021 18:29:11
User entered 'latuda'	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:29:05

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 18:29:19
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Apr 2021 18:29:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	02 Apr 2021 18:29:05
	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'AE# 3 bipolar disorder'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:29:05

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '20'	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Topical (TOPICAL)'	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '20 Jan 2021'	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 18:29:19
User entered 'Yes (Y)' reason for change: Data Entry Error	System	02 Apr 2021 18:29:19
User opened query 'Data is required. Please complete.' (Site from System).	lynn yauch (b) (4)	02 Apr 2021 18:29:19
User entered empty.	(b) (4)	
	System	02 Apr 2021 18:29:05
	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:29:05
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 18:29:05

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 18:29:05

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 18:29:05

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Apr 2021 10:01:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 10:01:01
Data point term sent to Coder	System	02 Apr 2021 21:41:20
Data point term sent to Coder	System	02 Apr 2021 21:13:05
Coding entries removed.	Jennifer Ruiz (b) (4) (b) (4)	02 Apr 2021 21:12:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 21:07:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 21:07:49
Data point term sent to Coder	System	02 Apr 2021 21:07:00
Data point term sent to Coder	System	02 Apr 2021 18:32:12
User entered 'flonase'	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:31:17

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'AE #4 (Right sided partial hearing loss) AND AE #5 (Right sided tinnitus)' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 21:41:19
User entered 'AE #4 and AE #5' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 21:12:50
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 21:06:01
User entered 'seasonal allergies(50mcg)'	lynn yauch (b) (4)	02 Apr 2021 18:31:17

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered '50' reason for change: Data Entry Error	(b) (4)	
	Jennifer Ruiz (b) (4)	02 Apr 2021 21:06:01
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 20:18:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 20:18:19
User entered '2' reason for change: Data Entry Error	Jennifer Ruiz (b) (4)	02 Apr 2021 20:18:19
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 18:31:17
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry	Jennifer Ruiz (b) (4)	02 Apr 2021 21:06:01
Error	(b) (4)	
User entered 'Other (OTHER)'	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty; reason for change Data Entry	Jennifer Ruiz (b) (4)	02 Apr 2021 21:06:01
Error	(b) (4)	
User entered 'spray'	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'twice daily (BID)' reason for change:	Jennifer Ruiz (b) (4)	02 Apr 2021 20:18:19
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Nasal (NASAL)'	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	02 Apr 2021 18:31:29
User entered '11 Jan 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Apr 2021 18:31:29
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	02 Apr 2021 18:31:17
User entered empty.	System	02 Apr 2021 18:31:17
	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 18:31:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 18:31:29
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	02 Apr 2021 18:31:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 18:31:17
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:31:17
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Apr 2021 20:18:19
User entered '1'	System	02 Apr 2021 18:31:17

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 18:31:17

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 18:31:17

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ESZOPICLONE, PRODUCTSYNONYM: LUNESTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Apr 2021 18:35:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Apr 2021 18:35:24
Data point term sent to Coder	System	02 Apr 2021 18:33:14
User entered 'lunesta'	lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:33:04

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'AE#6 insomnia'	(b) (4) lynn yauch (b) (4) (b) (4)	02 Apr 2021 18:33:04

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '1'	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'mg (mg)'	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'once daily (QD)'	(b) (4) lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
User entered 'Oral (ORAL)'	(b) (4) lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '15 Feb 2021'	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	05 Apr 2021 13:10:19
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	02 Apr 2021 18:33:04
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 18:33:04

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 18:33:04

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Apr 2021 18:33:04

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 20:17:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:17:25
Data point term sent to Coder	System	06 Apr 2021 20:15:57
User entered 'Lamotrigine'	Jennifer Ruiz (b) (4) (b) (4)	06 Apr 2021 20:15:20

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered 'No (N)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered 'Depression'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered '200'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered 'mg (mg)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'once daily (QD)'	(b) (4)	
	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered 'Oral (ORAL)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered '01 Jan 2014'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered '0'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered empty.	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
	(b) (4)	
User entered 'No (N)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:15:20
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:15:20

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 20:15:20

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 20:15:20

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 20:18:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 20:18:26
Data point term sent to Coder	System	06 Apr 2021 20:16:59
User entered 'Tylenol'	Jennifer Ruiz (b) (4) (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'No (N)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'Pain at injection site'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered '250'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'mg (mg)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered empty.	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'as needed (PRN)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered empty.	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'Oral (ORAL)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered empty.	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered '04 Oct 2020'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered '0'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'No (N)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered '04 Oct 2020'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:47
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User entered empty.	System	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User entered empty.	System	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:12
User entered empty.	System	06 Apr 2021 20:16:12

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 18:21:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 18:21:54
Data point term sent to Coder	System	23 Apr 2021 18:21:05
User entered 'Seroquel'	Chana Hines (b) (4) (b) (4)	23 Apr 2021 18:20:49

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:21:00
User entered 'No (N)' reason for change: Data Entry Error	System	23 Apr 2021 18:21:00
User opened query 'Data is required. Please complete.' (Site from System).	Chana Hines (b) (4)	23 Apr 2021 18:21:00
User entered empty.	(b) (4)	
	System	23 Apr 2021 18:20:49
	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'AE #6 (Insomnia)'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered '25' reason for change: Data Entry	Chana Hines (b) (4)	23 Apr 2021 18:22:40
Error	(b) (4)	
User entered '5'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'mg (mg)'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'once daily (QD)'	(b) (4)	
	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'Oral (ORAL)'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered '23 Mar 2021' reason for change: Data Entry Error	Chana Hines (b) (4)	23 Apr 2021 18:22:40
	(b) (4)	
User entered '20 Feb 2021'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered '0'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'Yes (Y)'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'No (N)'	Chana Hines (b) (4)	23 Apr 2021 18:20:49
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:20:49

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:20:49

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:20:49

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPIRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 18:23:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 18:23:58
Data point term sent to Coder	System	23 Apr 2021 18:23:07
User entered 'Abilify'	Chana Hines (b) (4) (b) (4)	23 Apr 2021 18:22:09

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'No (N)'	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'AE #2 (Worsening Depression)'	Chana Hines (b) (4)	23 Apr 2021 18:22:58
reason for change: Data Entry Error	(b) (4)	
User entered 'AE #2'	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered '5'	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered 'mg (mg)'	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'once daily (QD)'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'Oral (ORAL)'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered '20 Feb 2021'	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered '0'	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'Yes (Y)'	(b) (4)	
	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
	(b) (4)	
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'No (N)'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:22:09
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:22:09

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:22:09

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 18:22:09

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: CARBOXAMIDE DERIVATIVES, PRODUCT: OXCARBAZEPINE, PRODUCTSYNONYM: TRILEPTAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Apr 2021 12:45:56
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 Apr 2021 12:45:56
Data point term sent to Coder	System	23 Apr 2021 18:25:11
User entered 'Trileptal'	Chana Hines (b) (4) (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'No (N)'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'Bipolar Depression'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered '150'	Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'mg (mg)'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:24:25
User entered 'once daily (QD)' reason for change: Data Entry Error	System	23 Apr 2021 18:24:25
User opened query 'Data is required. Please complete.' (Site from System).	Chana Hines (b) (4)	23 Apr 2021 18:24:25
User entered empty.	(b) (4)	
	System	23 Apr 2021 18:24:16
	Chana Hines (b) (4)	23 Apr 2021 18:24:16
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered empty.	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'Oral (ORAL)'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered empty.	Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'UN Jul 2020' reason for change: Data Entry Error	(b) (4)	
	Chana Hines (b) (4)	23 Apr 2021 18:24:39
User entered '30 Jul 2020'	(b) (4)	
	Chana Hines (b) (4)	23 Apr 2021 18:24:16
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered '0'	(b) (4) Chana Hines (b) (4) (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'No (N)'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered '23 Mar 2021'	(b) (4) Chana Hines (b) (4)	23 Apr 2021 18:24:16
	(b) (4)	

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Michele Reynolds (b) (4)	26 Apr 2021 13:58:46
User entered 'No (N)'	Chana Hines (b) (4)	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User entered '1'	System	23 Apr 2021 18:24:25
User entered empty.	System	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User entered '1'	System	23 Apr 2021 18:24:25
User entered empty.	System	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 12 Aug 2021 13:39:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User entered '804 (804)'	System	23 Apr 2021 18:24:25
User entered empty.	System	23 Apr 2021 18:24:16

US3922074

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:39:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:38:18
	(b) (4)	
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	07 Dec 2020 18:22:53
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	07 Dec 2020 18:15:16
User entered 'No (N)'	Cristina Puig (b) (4)	04 Sep 2020 20:55:48
	(b) (4)	